Agenda Item B1

Legislation Update

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State of California Department of Consumer Affairs

Memorandum

To: Legislation & Regulation Committee Date: January 19, 2006

From: Jan E. Perez
Legislation and Regulation Coordinator

Subject: Legislation Report

The Legislature reconvened on January 4, 2006 for the 2006 Legislative Session. As of January 19, 2006 only one bill has been introduced that is of interest to the board, AB 123 (Nunez) Medicare Part D. Currently, there are eight bills with board positions and six bills on the board's watch list that are carry over bills from last year. The Legislature has until January 31st to move AB 72, AB 657, SB 19, and SB 152 from their house of origin. If these bills are not passed out of their house of origin then the bills are considered dead for the remainder of the session.

Attached is a copy of the Legislative calendar for 2006, Legislative Update for committee action, and copies of the bills and bill analysis.

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2006 Legislative Session Calendar

January 2006

Sun	Mon	Tue	Wed	Thurs	Fri	Sat
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30	31				

Jan. 4 Legislature reconvenes.
Jan. 10 Budget must be submitted by Governor.
Jan. 13 Last day for policy committees to hear bills introduced in their house in 2005.
Jan. 31 Last day for each house to pass bills introduced in 2005 in their house.

February 2006

Sun	Mon	Tue	Wed	Thurs	Fri	Sat
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28				

Feb. 24 Last day for bills to be introduced.

March 2006

Sun	Mon	Tue	Wed	Thurs	Fri	Sat
			1	2	3	4
5	6	7	8	9	10	11
12	13	14	15	16	17	18
19	20	21	22	23	24	25
26	27	28	29	30	31	

2006 Legislative Session Calendar

April 2006

Sun	Mon	Tue	Wed	Thurs	Fri	Sat
30						1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29

April 6-16 Spring Recess.
April 17 Legislature reconvenes.

May 2006

Sun	Mon	Tue	Wed	Thurs	Fri	Sat
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

May 30 – June 2 Floor session only.

June 2006

Sun	Mon	Tue	Wed	Thurs	Fri	Sat
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	

June 2 Last day for bills to be passed out of the house of origin.
June 15 Budget must be passed by midnight.
June 30 Last day for policy committees to meet and report bills.

2006 Legislative Session Calendar

July 2006

Sun	Mon	Tue	Wed	Thurs	Fri	Sat
30	31					1
2	3	4	5	6	7	8
9	10	11	12	13	14	15
16	17	18	19	20	21	22
23	24	25	26	27	28	29

July 7 Aug. 6 Summer Recess.

August 2006

Sun	Mon	Tue	Wed	Thurs	Fri	Sat
		1	2	3	4	5
6	7	8	9	10	11	12
13	14	15	16	17	18	19
20	21	22	23	24	25	26
27	28	29	30	31		

Aug. 7 Legislature reconvenes.
Aug. 18 Last day for fiscal committees to meet and report bills to floor.
Aug. 21-31 Floor session only.
Aug 31. Final recess begins at end of this day's session.

September 2006

Sun	Mon	Tue	Wed	Thurs	Fri	Sat
					1	2
3	4	5	6	7	8	9
10	11	12	13	14	15	16
17	18	19	20	21	22	23
24	25	26	27	28	29	30

Sep. 30 Last day for Governor to sign or veto bills passed by the Legislature.

Dec. 4, 2006, 2007-08 Legislative Session Convenes.

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Legislation of 2005 Introduced Bills

NO ACTION

SCR 49 (Chapter 123, 2005)
The measure requires the Legislature to create a panel to study the causes of medication errors and recommend changes in the health care system that would reduce errors associated with the delivery of prescription and over-the-counter medication to consumers. The measure requires the panel to convene by October 1, 2005 and to submit a preliminary report by March 1, 2006 to the Senate Committee on Health and a final report by June 1, 2006.

To date, the Medications Errors Panel has not been formed. The Senate Rules Committee is in the process of accepting applications for the panel and Senate Rules staff anticipates the panel forming by the end of January 2006. Given the late start the panel it is unlikely to meet the deadlines for the reports called for in the legislation and will likely establish new due dates once the panel meets.

Board member Powers has been nominated by Senator Speier as a public member of the committee.

Status of Bills with a Board Position

FOR ACTION

AB 595 (Negrete McLeod) Pharmacy: Compounding of Prescription Drugs Board-Sponsored Bill
Board Position: **Support**
Status: **Senate floor, inactive file**

Summary: The bill would define compounding of a prescription drug for the purposes of the Pharmacy Law and would make other related changes in that regard.

Note: In August, Department of Health Services (DHS) took an oppose position on the May 26, 2005 version of the bill. The board is working to resolve the opposition.

AB 21 (Levine) Pharmacists: Practice Requirements
Board Position: **Oppose**
Status: **Senate Health Committee**

Summary: This bill would require a pharmacist to dispense a prescription except in specified circumstances. The bill would allow a pharmacist to decline on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request only if he or she satisfies certain conditions. The bill would make a violation of those provisions unprofessional conduct and would also make harassment, as specified, of a patient by a pharmacist unprofessional conduct, subject to disciplinary action by the board. (B&P 4069)

Note: SB 644 (Chapter417, Statutes of 2005) was a related bill that stalled AB 21 in the Senate

AB 225 (Negrete McLeod) Electronic Prescription Information
Board Position: **Support if Amended**
Status: **Senate Business, Professions And Economic Development Committee**

Summary: This bill would modify B&P section 650 to allow health care professionals to receive nonmonetary remuneration, in the form of hardware, software, or information technology and training services, necessary and used solely to receive and transmit electronic prescription information in accordance with the standards set forth in Section 1860D-4(e) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395w-104), in specified circumstances.

Amendment: Require the prescriber, prior to the electronic transmitting of a prescription, to offer to transmit the prescription to a pharmacy of the patient's choice.

AB 657 (Karnette) Pharmacies: Prescription Containers: Labels
Board Position: **Support**
Status: **Senate Business, Professions And Economic Development Committee**

Summary: This bill would revise the prescription labeling requirements to require a container to be labeled with, among other things, the "intended purpose" for which the drug was prescribed, if the intended purpose is listed on the prescription.

AB 896 (Matthews) Clinical Laboratories
Board Position: **Support**
Status: **Assembly Business and Professions Committee**

Summary: This bill would authorize a pharmacist to serve as a laboratory director of a clinical laboratory that provides routine patient assessment procedures, as defined, under specified conditions.

SB 152 (Speier) Pseudoephedrine
Board Position: **Oppose**
Status: Senate Business, Professions And Economic Development Committee

Summary: The bill would require 1) pseudoephedrine products to be sold in a pharmacy and by a pharmacist or pharmacy technician; 2) pseudoephedrine to be stored in a locked area in view of the pharmacist; 3) limit the quantity of product sold to no more than nine grams of pseudoephedrine in a within any 30 day period; 3) the purchaser produce photo identification; and 4) the purchaser to sign a document with specific information about the transaction. Senate Bill 152 would place these provisions in B&P 4051.1.

SB 401 (Ortiz) Medical information: Pharmacies: Marketing
Board Position: **Oppose Unless Amended**
Status: **Assembly Health Committee**

Summary: This bill would define marketing to include written communication that is provided by a pharmacy to a patient about a different drug or treatment than that being dispensed by the pharmacy and that is paid for, or sponsored by, a manufacturer, labeler, or distributor of prescription drugs.
Amendments: 1) Provide a means for consumers to opt out of receiving advertisements with their prescriptions. 2) Require advertisements to be marked with the entity paying for the advertisement.

SB 592 (Aanestad) Acute Care Hospitals: Inpatient Pharmacy Technician Services
Board Position: **Support**
Status: Assembly **Health Committee**

Summary: This bill would permit general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians (TCT) filling floor stock, ward stock, and unit dose cassettes.

Status of 2005 Bills of Interest

AB 71 (Chan) Pharmaceuticals: Adverse Drug Reactions: Office of CA Drug Safety
Status: **Senate Health Committee**

Summary: This bill would establish the Office of California Drug Safety Watch, which would require the construction of a public database of adverse prescription drug reactions.

AB 72 (Frommer) Prescription Drugs: Clinical Trials
Status: **Senate Health Committee**

Summary: This bill would establish the Patient Safety and Drug Review Transparency Act in order to ensure that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers.

AB 74 (Gordon) California Rx Prescription Drug Hotline
Status: **Senate Health Committee**

Summary: This bill would establish a hotline that state residents could call for information about state and federal prescription drug discount programs.

AB 75 (Frommer) Pharmaceutical Assistance Program
Status: **Senate Health Committee**

Summary: This bill would establish a prescription drug discount program for low-income state residents.
Note: AB 75 is similar to Proposition 79, which was rejected by voters in November 2006.

SB 19 (Ortiz) California Rx Program

Status: **Senate Rules**

Summary: This bill is sponsored by the Governor and would establish the California Rx Program to negotiate for lower price prescription drugs for lower income Californians.

Note: SB 19 is similar to Proposition 78, which was rejected by voters in November 2006.

SB 380 (Alquist) Drugs: Adverse Event Reporting

Status: **Assembly Floor – inactive file**

Summary: This bill would require a licensed health professional, (a physician and surgeon, dentist, or pharmacist), and a health facility, (a hospital or clinic), to report all suspected serious adverse drug events that are spontaneous or observed in medical practice to the FDA's MedWatch program.

Senate Concurrent Resolution No. 49

RESOLUTION CHAPTER 123

Senate Concurrent Resolution No. 49—Relative to medication errors.

[Filed with Secretary of State September 14, 2005.]

LEGISLATIVE COUNSEL'S DIGEST

SCR 49, Speier. Medication errors panel.

This measure would create a panel to study the causes of medication errors and recommend changes in the health care system that would reduce errors associated with the delivery of prescription and over-the-counter medication to consumers. The measure would require the panel to convene by October 1, 2005, and to submit to the Assembly Committee on Health and the Senate Committee on Health a preliminary report by March 1, 2006, and a final report by June 1, 2006.

WHEREAS, Numerous studies establish that medication errors cause injury and death to patients and consumers; and

WHEREAS, The Institute of Medicine estimates the cost for treatment of drug-related morbidity and mortality may run nearly $77 billion a year nationally; and

WHEREAS, Research demonstrates that most injuries resulting from medication errors are not the fault of any individual health care professional, but rather represent the failure of a complex health care system; and

WHEREAS, The Federal Food and Drug Administration has approved 122 chemical compounds since 2002, and over 17,000 existing trade and generic names of products exist, many of which sound alike or are spelled alike; and

WHEREAS, These products are also packaged and distributed in similar shapes and forms; and

WHEREAS, The demand for prescription drugs is expected to substantially increase; and

WHEREAS, Medication errors occur in all settings in which prescription drug products are prescribed, dispensed, furnished, ordered, or otherwise provided; and

WHEREAS, Many factors contribute to a poor understanding by many consumers and patients about their prescriptions, including frequent switching of generic brands that are each different colors and shapes so that the same drug looks different and confuses the patient making it hard to easily spot mistakes; overworked pharmacists; reduced time with physicians for patients to be given important drug information; patients seeing multiple physicians that may be unaware of each other's care plans;

patients often using vitamins, herbs, and over-the-counter drugs that can react with the medications they take and that both the physician and pharmacist do not know about; and

WHEREAS, Research has demonstrated that improved communication between patients and their health professionals is the most effective means of reducing errors and drug misadventures and improving health care outcomes; now, therefore, be it

Resolved by the Senate of the State of California, the Assembly thereof concurring, That a special panel be formed to study causes of medication errors; and be it further

Resolved, That the Legislature shall convene the panel no later than October 1, 2005; and be it further

Resolved, That the panel shall recommend improvements, additions, or changes to be constructed and implemented for the significant improvement of the health care system by reducing errors associated with the delivery of prescription and over-the-counter medications to consumers; and be it further

Resolved, That the Speaker of the Assembly shall appoint to the panel a member of the faculty of a school of pharmacy, a representative of the California Pharmacists Association, a representative of the California Association of Health Plans, a representative of the Pharmaceutical Research and Manufacturers of America, a member of the California Medical Association, a member or representative of the Assembly Democratic Caucus, a member or representative of the Assembly Republican Caucus, and a consumer representative; and be it further

Resolved, That the Senate Committee on Rules shall designate the chair and appoint to the panel a representative of the California Retailers Association Chain Drug Committee, a member of the California Society of Hospital Pharmacists, a representative of the Generic Pharmaceutical Association, a representative of a public health organization, a member of the California Nurses Association, a representative of AARP, a representative of the Consumer Health Care Products Association, a member or representative of the Senate Democratic Caucus, and a member or representative of the Senate Republican Caucus; and be it further

Resolved, That the members of the panel shall not receive compensation, but shall be reimbursed from private sources for necessary travel expenses for the purpose of attending meetings of the panel, including any public meetings that the panel schedules, and the panel shall be funded by private sources; and be it further

Resolved, That the panel shall submit to the Senate Committee on Health and the Assembly Committee on Health a preliminary report of its conclusions and recommendations by March 1, 2006, and a final report of its conclusions and recommendations no later than June 1, 2006; and be it further

Resolved, That the Secretary of the Senate transmit copies of this resolution to the author for appropriate distribution.

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AMENDED IN SENATE MAY 26, 2005

AMENDED IN ASSEMBLY APRIL 18, 2005

AMENDED IN ASSEMBLY MARCH 29, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 595

Introduced by Assembly Member Negrete McLeod

February 17, 2005

An act to amend Section 4051 of, to add Section 4019.5 to, to repeal Section 4033 of, and to repeal and add Section 4123 of, the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 595, as amended, Negrete McLeod. Pharmacy: compounding of prescription drugs.

Existing law, the Pharmacy Law, provides for the licensing and regulation by the California State Board of Pharmacy of pharmacists, pharmacies, and other related practices and makes a violation of that law a crime. The Pharmacy Law defines various terms for its purposes, including "manufacturer."

This bill would delete the definition of manufacturer. The bill would define compounding of a prescription drug for the purposes of the Pharmacy Law and would make other related changes in that regard. Because the bill would specify requirements for compounded drug products under the Pharmacy Law, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state.

Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4019.5 is added to the Business and Professions Code, to read:

4019.5. (a) "Compounding" means any of the following activities occurring in a pharmacy pursuant to a prescription:

(1) Altering the dosage form or delivery system of a drug.

(2) Altering the strength of a drug.

(3) Combining components or active ingredients.

(4) Preparing a drug product from bulk chemicals.

(b) "Compounding" shall not include the reconstitution of a drug pursuant to the manufacturer's direction for oral, rectal, or topical administration.

~~(c) This section shall not apply to over-the-counter drugs or nonprescription drugs.~~

SEC. 2. Section 4033 of the Business and Professions Code is repealed.

SEC. 3. Section 4051 of the Business and Professions Code is amended to read:

4051. (a) Except as otherwise provided in this chapter, it is unlawful for any person to compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription pursuant to Section 4040 of a prescriber unless he or she is a pharmacist under this chapter.

(b) Notwithstanding any other law, a pharmacist may authorize the initiation of a prescription, pursuant to Section 4052, and otherwise provide clinical advice or information or patient consultation if all of the following conditions are met:

(1) The clinical advice or information or patient consultation is provided to a health care professional or to a patient.

(2) The pharmacist has access to prescription, patient profile, or other relevant medical information for purposes of patient and clinical consultation and advice.

(3) Access to the information described in paragraph (2) is secure from unauthorized access and use.

SEC. 4. Section 4123 of the Business and Professions Code is repealed.

SEC. 5. Section 4123 is added to the Business and Professions Code, to read:

4123. (a) A compounded drug product shall only be dispensed or furnished to a patient pursuant to a prescription meeting the requirements of Section 4040.

(b) A compounded drug product shall only be dispensed or furnished to a patient where the prescription has been generated solely within an established professional relationship between the prescriber, patient, and dispensing pharmacy.

(c) A pharmacy may conduct anticipatory compounding of a drug product in limited quantity, as defined by regulation of the board, before receipt of a prescription order for that drug product, where the quantity of each drug product compounded in anticipation of receipt of prescription orders is based on a documented history of receipt of prescription orders generated solely within an established professional relationship between prescribers, patients of the pharmacy, and the pharmacy.

(d) A pharmacy may contract with another pharmacy to compound drug products on behalf of its patients.

(e) A pharmacy may only base its anticipatory compounding on a documented history of prescription orders received for its own patients or customers, and not those patients or customers of pharmacies with which it has a contractual relationship.

(f) Notwithstanding any other provision of this chapter, a pharmacist may do both of the following:

(1) Compound a drug product pursuant to a prescription, for delivery to another pharmacy pursuant to a contract for the purpose of dispensing or furnishing the drug product to the patient named in the prescription, provided that the drug is not compounded prior to the receipt of the prescription.

(2) Repackage a drug previously dispensed to the patient at the request of the patient or the patient's agent.

~~(g) This section shall not apply to over-the-counter drugs or nonprescription drugs.~~

SEC. 6. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because

the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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SENATE RULES COMMITTEE Office of Senate Floor Analyses 1020 N Street, Suite 524 (916) 445-6614 Fax: (916) 327-4478	AB 595

THIRD READING

Bill No: AB 595
Author: Negrete McLeod (D)
Amended: 5/26/05 in Senate
Vote: 21

SENATE. BUS., PROF. AND ECON. DEV COMMITTEE : 5-0, 6/20/05
AYES: Figueroa, Campbell, Florez, Murray, Simitian
NO VOTE RECORDED: Aanestad, Morrow

SENATE APPROPRIATIONS COMMITTEE : Senate Rule 28.8

ASSEMBLY FLOOR : 73-0, 5/05/05 (Passed on Consent) - See last page for vote

SUBJECT : Pharmacy: compounding of prescription drugs

SOURCE : California State Board of Pharmacy

DIGEST : This bill defines compounding of prescription drugs and establishes standards for pharmacies that compound drug products for the patients.

ANALYSIS :

Existing Law

1. Provides for the licensing and regulation of pharmacists and pharmacies and the practice of pharmacy by the State Board of Pharmacy (Board).

CONTINUED

2. Defines "manufacturer" as a person who prepares, derives, produces, compounds, or repackages any drug or device except a pharmacy that manufacturers on the immediate premises where the drug or device is sold to the ultimate consumer.

3. Specifies that "manufacturer" shall not mean a pharmacy compounding a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy for the purpose of delivering or administering the drug to the patient or patients named in the prescription provided that the drug is not prepared prior to receipt of the prescription.

4. Specifies that "manufacturer" shall not mean a pharmacy that, at a patient's request, repackages a drug previously dispensed to the patient, or to the patient's agent, pursuant to a prescription.

5. Provides that it is unlawful for any person to manufacture, compound, furnish, sell, or dispense any dangerous drug or dangerous device, or to dispense or compound any prescription of a prescriber, as required, unless he or she is a pharmacist.

6. Requires that any pharmacy that contracts to compound a drug for parenteral therapy, pursuant to a prescription, for delivery to another pharmacy shall report the contractual arrangement to the Board within 30 days of commencing the compounding.

7. Requires any pharmacy, in order to compound injectable sterile drug products, to obtain a license from the Board of Pharmacy to compound injectable sterile drug products and specifies other requirements as it pertains to compounding injectable drug products.

This bill:

1. Defines compounding as any of the following activities occurring in a pharmacy relating to a prescription:

   A. Altering the dosage form, or delivery system of a drug

   B. Altering the strength of a drug.

C. Combining components of active ingredients.

D. Preparing a drug product from bulk chemicals.

2. Excludes from the definition of "compounding" the reconstruction of a drug pursuant to the manufacturer's direction of oral, rectal, or topical administration.

3. Requires that a compounded drug product be dispensed or furnished to a patient only pursuant to a prescription or where the prescription has been generated solely within an established professional relationship between the prescriber, patient, and dispensing pharmacy.

4. Allows a pharmacy to conduct anticipatory compounding of a drug product in limited quantity, as specified, and allows a pharmacy to base its anticipatory compounding on a documented history of prescription orders received for its own patients or customers, and not those patients or customers of pharmacies with which it has a contractual relationship.

5. Allows a pharmacy to contract with another pharmacy to compound drug products on behalf of its patients.

6. Allows a pharmacist to do both of the following:

A. Compound a drug product pursuant to a prescription, for delivery to another pharmacy pursuant to a contract for the purpose of dispensing or furnishing the drug product to the patient named in the prescription, as long as the drug is not compounded before receipt of the prescription.

B. Repackage a drug previously dispensed to the patient at the request of the patient or the patient's agent.

7. Deletes the definition of manufacturer and the requirement for a pharmacy that contracts to compound a drug for parenteral therapy to report the arrangement to

the Board.

8. Makes other technical non-substantive changes.

Background

Drug Compounding . Drug compounding involves the mixing,

combining, or altering of ingredients to create a customized medication for an individual patient. Some of the products commonly compounded include lotions, ointments, creams, gels, suppositories, and intravenously administered fluids and medications. Some compounded drugs, like intravenously administered chemotherapy drugs, are sterile products that require special safeguards to prevent injury or death to patients receiving them. These safeguards include cleaner facilities, specific training for pharmacy personnel, and testing of the compounded drug for sterility. According to the FDA, compounding occurs because there are drugs for certain conditions that are not made by manufacturers and even if a drug is mass-produced for a medical condition, patients might need a custom-made version for various reasons. However, compounding has its risks. Background information revealed that several compounding cases resulted in serious illness and deaths and raised concerns about oversight to ensure safety and quality of compounded drugs.

Compounding Oversight and Development of this Proposal . According to the Board, the FDA and Department of Health Services (DHS) consider compounding by a pharmacy to be drug manufacturing. The DHS licenses and the FDA registers licensees' businesses engaged in certain compounding activities. Under federal and state law, any manipulation of a drug product or component, which alters its original state including repackaging or relabeling, constitutes manufacturing, including what has been traditionally considered pharmacy compounding. However, federal and state drug laws, including California's Pharmacy Law, recognize compounding as a proper function of pharmacy practice and exempt pharmacies engaged in legitimate compounding from licensure or registration as manufacturers. The Board has jurisdiction over anyone who handles or prepares a dangerous drug, whether for sale, retail or otherwise in California. The FDA and DHS have

authority over manufacturing, including compounding, even by those exempt from licensure and registration, but, in the exercise of their discretion, both the FDA and DHS have chosen to target pharmacy compounding that occurs outside the bounds of traditional pharmacy practice and leave the day-to-day regulation of traditional pharmacy practices to state boards of pharmacy.

In 1992, FDA issued a compliance policy guide that delineated FDA's enforcement policy on pharmacy compounding. That guide remained in effect until 1997, when Congress enacted the Food and Drug Administration

Modernization Act of 1997. The new law clarified the status of pharmacy compounding under federal law. The FDA Modernization Act of 1997 defined the limits of legitimate compounding and included a section exempting drugs compounded on a customized basis for an individual patient from key portions of the Food Drug and Cosmetic Act (FDCA), if certain criteria were met. However, a 2002 decision by the U. S. Supreme Court found the section dealing with drug compounding contained unconstitutional restrictions on commercial speech (i.e., prohibitions on soliciting prescription for and advertising specific compounded drugs) and held the entire section of law as invalid. In May 2002, the FDA issued a compliance guide on pharmacy compounding to represent its current position which indicated that the FDA will generally defer to state authorities in dealing with less significant violations of the FDCA, and expects to work cooperatively with the states in coordinating investigations, referrals, and follow-up actions. The practical effect of the FDA's compliance policy was to delegate to states the authority to regulate drug compounding when it is done to meet the unique needs of individual patients.

Previous Legislation

SB 293 (Torlakson), Chapter 827, Statutes of 2001, required the Board to adopt regulations establishing standards for compounding injectable sterile drug products in a pharmacy, required some pharmacies that compound these drug products to be specially licensed, and provided for inspection and investigations of compounding pharmacies. This 2001, legislation was the result of a case where contaminated

drugs compounded in a pharmacy led to the deaths of three patients and the hospitalization of many others.

FISCAL EFFECT : Appropriation: No Fiscal Com.: Yes Local: Yes

SUPPORT : (Verified 7/11/05)

State Board of Pharmacy (source)

ASSEMBLY FLOOR :
AYES: Aghazarian, Arambula, Baca, Bass, Benoit, Berg, Bermudez, Blakeslee, Bogh, Calderon, Canciamilla, Chan, Chavez, Chu, Cogdill, Cohn, Coto, Daucher, De La Torre, DeVore, Dymally, Emmerson, Evans, Frommer, Garcia, Goldberg, Hancock, Harman, Haynes, Shirley Horton,

Houston, Huff, Jones, Karnette, Keene, Klehs, Koretz, La Malfa, La Suer, Laird, Leno, Lieber, Liu, Matthews, McCarthy, Montanez, Mountjoy, Mullin, Nakanishi, Nation, Nava, Negrete McLeod, Niello, Oropeza, Parra, Pavley, Plescia, Richman, Ridley-Thomas, Ruskin, Saldana, Salinas, Spitzer, Strickland, Torrico, Tran, Umberg, Vargas, Villines, Walters, Wyland, Yee, Nunez
NO VOTE RECORDED: Gordon, Jerome Horton, Leslie, Levine, Maze, Sharon Runner, Wolk

JJA:cm 7/11/05 Senate Floor Analyses

SUPPORT/OPPOSITION: SEE ABOVE

**** END ****

AMENDED IN SENATE JUNE 15, 2005

AMENDED IN ASSEMBLY APRIL 13, 2005

AMENDED IN ASSEMBLY MARCH 29, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 21

Introduced by Assembly Member Levine
(Coauthors: Assembly Members Berg, Chavez, Cohn, De La Torre, Evans, Goldberg, Jones, Koretz, Laird, Lieber, Montanez, Nava, and Ruskin)

December 6, 2004

An act to add ~~Section 4069~~ *Sections 4069 and 4316* to the Business and Professions Code, relating to pharmacy.

LEGISLATIVE COUNSEL'S DIGEST

AB 21, as amended, Levine. Pharmacists: ~~dispensing~~ *practice* requirements.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy and makes a violation of that law a crime *and subject to the assessment of a fine by the board.* Under existing law, a prescription may be lawfully dispensed only by a pharmacist, unless otherwise specified by the Pharmacy Law.

This bill would require a pharmacist to dispense a prescription except in specified circumstances. The bill would allow a pharmacist to decline on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request only if he or she satisfies certain conditions. The bill would make a violation of ~~its~~ *those* provisions unprofessional conduct *and would also make harassment, as specified,*

of a patient by a pharmacist unprofessional conduct, subject to disciplinary action by the board.

Because the bill would specify ~~an~~ additional ~~requirement~~ *violations* under the Pharmacy Law, ~~a violation of~~ which would be *punishable as* a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. This act shall be known and may be cited as the Women's Contraceptive and Pharmaceutical Freedom Act of 2005.

~~SECTION 1.—~~

SEC. 2. Section 4069 is added to the Business and Professions Code, to read:

4069. (a) Notwithstanding any other provision of law, a pharmacist shall dispense a lawful prescription unless one of the following circumstances exists:

(1) The pharmacist determines, based on his or her professional training and judgment, that dispensing the prescription is contrary to law or, after consulting with the patient's prescriber, that it is contraindicated for the patient.

(2) The pharmacy does not have the prescribed trade or brand name drug in stock. The pharmacist shall offer the patient another drug product, if available, with the same active chemical ingredients of the same strength, quantity, and dosage form and of the same generic drug name, as determined by the United States Adopted Names and accepted by the federal Food and Drug Administration, as the prescribed drug product and follow the procedure or protocol described in Section 4073.

(3) (A) The pharmacist elects to refuse on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request. A pharmacist may decline to dispense a drug on these grounds

only after notifying his or her employer in writing of his or her objections. The pharmacist shall provide this notification upon acceptance of employment and immediately after any change to that decision.

(B) An employer shall, upon receipt of the notification described in subparagraph (A), establish a policy and protocol to accommodate the patient's ~~needs~~ *need* for the drug.

(b) An employer shall not withdraw an offer of employment or terminate employment based on the notification or change in the notification, as described in subparagraph (A) of paragraph (3) of subdivision (a).

(c) A violation of this section by a pharmacist constitutes unprofessional conduct for the purposes of Section 4301, subject to disciplinary action by the board.

SEC. 3. Section 4316 is added to the Business and Professions Code, to read:

4316. It shall constitute unprofessional conduct and a violation of this chapter for a pharmacist to harass a patient by engaging in extreme or outrageous conduct and intentionally causing the patient emotional distress or by engaging in conduct with reckless indifference to the likelihood of causing the patient emotional distress. For these purposes, the emotional distress shall be actual and severe as determined by a reasonable person.

~~SEC. 2.—~~

SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 21 **VERSION: AMENDED JUNE 15, 2005**

AUTHOR: LEVINE **SPONSOR: LEVINE**

RECOMMENDED POSITION: OPPOSE

SUBJECT: PHARMACISTS: PRACTICE REQUIREMENTS

Existing Law:

1) Permits pharmacists to dispense emergency contraception (EC) without a prescription if a protocol is established with a prescriber or the protocol established by the board. (B&P 4052(8))

2) Establishes procedures for dispensing EC without a prescription. (CCR 1746)

3) Requires a pharmacist who declines to distribute EC to refer the patient to another EC provider. (CCR 1746)

4) Requires the board to take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. (B&P 4301)

This Bill:

1) Establishes the Women's Contraceptive and Pharmaceutical Freedom Act of 2005. (B&P 4069 Added)

2) States that it shall constitute unprofessional conduct and a violation of this chapter for a pharmacist to harass a patient by engaging in extreme or outrageous conduct and intentionally causing the patient emotional distress or by engaging in conduct with reckless indifference to the likelihood of causing the patient emotional distress. For these purposes, the emotional distress shall be actual and severe as determined by a reasonable person. (B&P 4316 Added)

3) Requires a violation of this section by a pharmacist to constitute unprofessional conduct for the purposes of Section 4301, subject to disciplinary action by the board. (B&P 4069 Added)

4) Requires a pharmacist to dispense a "lawful" prescription unless one of the following circumstances exists:

a. The pharmacist determines, based on his or her professional training and judgment, that dispensing the prescription is contrary to law or, after consulting with the patient's prescriber, that it is contraindicated for the patient.

b. The pharmacy does not have the prescribed trade or brand name drug in stock. The pharmacist shall offer the patient another drug product, if available, with the same active

chemical ingredients of the same strength, quantity, and dosage form and of the same generic drug name, as determined by the United States Adopted Names and accepted by the federal Food and Drug Administration, as the prescribed drug product and follow the procedure or protocol described in Section 4073.

c. The pharmacist elects to refuse on ethical, moral, or religious grounds to dispense a drug pursuant to a lawful request.

   i. A pharmacist may decline to dispense a drug on these grounds only after notifying his or her employer in writing of his or her objections.

   ii. The pharmacist shall provide this notification upon acceptance of employment and immediately after any change to that decision.

(B&P 4069 Added)

5) Requires an employer, upon receipt of a pharmacist objections, to establish a policy and protocol to accommodate the patient's need for the drug. (B&P 4069 Added)

6) Does not permit an employer to withdraw an offer of employment or terminate employment based on the notification or change in the notification. (B&P 4069 Added)

Comment:

1) Author's Intent. The author's intent is to insure that pharmacists do not refuse to dispense EC to patients. Since enactment of SB 644 (Chapter417, Statutes of 2005), AB 21 has stalled in the Senate.

2) In the News. The issue on whether or not a pharmacist has a right to refuse to fill a prescription has been debated in the news and in state legislatures over the last year. The Washington Post reports that twelve states either have laws or are considering laws that would allow a pharmacist not to fill a prescription. While much of the debate has centered on birth control and EC, there are increasing news reports and web postings that indicate this issue is likely to expand into other moral issues such as assisted suicide, sterile needle programs, and pain management.

3) Emotional Distress. AB 21 adds an emotional distress provision to pharmacy law. Emotional distress provisions are not uncommon in professions law such as those governing Marriage and Family Therapists, Licensed Vocational Nurses, and Licensed Clinical Social Workers, where a licensee has the power to misuse their position and inflict emotional distress on a patient. The practice of pharmacy differs from other professions where a pharmacist interacts with a wide range of patients and customers. Some of these patients are on medications that may alter their perception of reality and others may be addicted to some medications and seeking to get more medications illegally. It is up to a pharmacist to use his or her best professional judgment under the law to either dispense or refuse to dispense a medication. Some patients may misinterpret a pharmacist's use of their judgment as causing emotional distress. In this situation, under the provision in AB 21 the patient can file can a claim with the board claiming a pharmacist has misused their position. The board believes that it currently has the powers it needs to take enforcement action against a pharmacist that misuses their position and the addition of an emotional distress provision to pharmacy law is unnecessary.

4) Enforcement. Enforcement of AB 21 would be consumer complaint driven. In 2004, the board did not receive any consumer complaints relating to a pharmacist's refusal to dispense EC. The June 15th amendments regarding unprofessional conduct and emotional distress may be difficult to enforce. If AB 21 is enacted the board anticipates that it will need to train its inspectors on the nuances of the law governing emotional distress.

5) Legislative History. Senate Bill 1169 (Chapter 900, Statutes of 2001) established the authority for pharmacists to dispense emergency contraception without a prescription. The board supported that legislation. SB 545 (Chapter 652, Statutes of 2003) clarified many of the provisions in SB 1169. The board took a neutral position on the bill.

SB 644 (Chapter417, Statutes of 2005) Dispensing Prescription Drugs And Devices, requires a health care licentiate to dispense drugs and devices pursuant to a lawful prescription or order except in specified circumstances, including on ethical, moral, or religious grounds asserted by the licentiate.

6) Federal Legislation. In April 2005, Senator Boxer introduced S 778, the Pharmacy Consumer Protection Act of 2005. S778 would require a pharmacist to fill a legal prescription unless the prescribed item is not in the pharmacy's stock, in which case the pharmacy would order such item without unnecessary delay or, if the patient prefers, the pharmacy would transfer the prescription to a local pharmacy of the patient's choice or return the prescription to the patient, at the patient's request. S 778 would not prohibit a pharmacist from refusing to dispense a prescribed item, in accordance with standard pharmacy practice, if there is a valid medical concern that such prescribed item will cause problems due to therapeutic duplications, drug-disease contraindications, drug interactions, incorrect dosage or duration of drug treatment, drug-allergy interactions, or drug abuse or misuse. S 778 has been referred to the Senate Finance Committee.

7) Support & Opposition.

Support: American Academy of Pediatrics, California District
California Medical Association
NARAL Pro-Choice California (if amended)
National Association of Social Workers, California Chapter
Planned Parenthood Affiliates of California (in concept)

Oppose: California Association for Health Services at Home (unless amended)
California Family Alliance
California Pharmacists Association (unless amended)
California Retailers Association (unless amended)
California Right to Life Committee, Inc.
California Society of Health-System Pharmacists
Traditional Values Coalition

9) History.

2005

June 22 In committee: Set first hearing. Failed passage. Reconsideration granted.
June 15 From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
June 15 Referred to Coms. on HEALTH and B., P. & E.D.
June 6 In Senate. Read first time. To Com. on RLS. for assignment.
June 2 Read third time, passed, and to Senate. (Ayes 52. Noes 25. Page 2096.)
May 9 Read second time. To third reading.
May 5 From committee: Do pass. (Ayes 12. Noes 5.) (May 4).
Apr. 27 From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 7. Noes 2.) (April 26).
Apr. 14 Re-referred to Com. on B. & P.
Apr. 13 Read second time and amended.
Apr. 12 From committee: Amend, do pass as amended, and re-refer to Com. onB. & P. (Ayes 10. Noes 3.) (April 5).
Mar. 30 Re-referred to Com. on HEALTH.

Mar. 29 From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Feb. 15 Referred to Coms. on HEALTH and B. & P.

2004
Dec. 7 From printer. May be heard in committee January 6.
Dec. 6 Read first time. To print.

AMENDED IN ASSEMBLY APRIL 7, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 225

Introduced by Assembly Member Negrete McLeod

February 3, 2005

An act to amend Section 650 of the Business and Professions Code, relating to healing arts.

LEGISLATIVE COUNSEL'S DIGEST

AB 225, as amended, Negrete McLeod. Electronic prescription information.

Existing law relative to insurance fraud makes it a crime for healing arts practitioners to receive money or other consideration for, or to engage in various related activities with respect to, the referral of patients, clients, or customers to any person, with certain exceptions.

This bill would, *upon the effective date of specified regulations adopted by the Secretary of the United States Department of Health and Human Services pursuant to the Medicare Prescription Drug, Improvement and Modernization Act of 2003,* exempt from these provisions ~~a licensed health care facility or licensed health care professional prescribing or dispensing medication~~ *specified entities* that ~~receives~~ *receive* nonmonetary remuneration necessary and used solely to receive and transmit electronic prescription information, *under certain conditions.*

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Section 650 of the Business and Professions Code is amended to read:

650. *(a)* Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code, the offer, delivery, receipt, or acceptance by any person licensed under this division or the Chiropractic Initiative Act of any rebate, refund, commission, preference, patronage dividend, discount, or other consideration, whether in the form of money or otherwise, as compensation or inducement for referring patients, clients, or customers to any person, irrespective of any membership, proprietary interest or coownership in or with any person to whom these patients, clients, or customers are referred is unlawful.

~~The~~

(b) The payment or receipt of consideration for services other than the referral of patients which is based on a percentage of gross revenue or similar type of contractual arrangement shall not be unlawful if the consideration is commensurate with the value of the services furnished or with the fair rental value of any premises or equipment leased or provided by the recipient to the payer.

~~Except~~

(c) Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code and in Sections 654.1 and 654.2, it shall not be unlawful for any person licensed under this division to refer a person to any laboratory, pharmacy, clinic (including entities exempt from licensure pursuant to Section 1206 of the Health and Safety Code), or health care facility solely because the licensee has a proprietary interest or coownership in the laboratory, pharmacy, clinic, or health care facility; provided, however, that the licensee's return on investment for that proprietary interest or coownership shall be based upon the amount of the capital investment or proportional ownership of the licensee which ownership interest is not based on the number or value of any patients referred. Any referral excepted under this section shall be unlawful if the prosecutor proves that there was no valid medical need for the referral.

~~Except~~

(d) (1) Except as provided in Chapter 2.3 (commencing with Section 1400) of Division 2 of the Health and Safety Code and in Sections 654.1 and 654.2, it shall not be unlawful ~~for a licensed health care facility, or a licensed health care professional prescribing or dispensing medication, to receive nonmonetary remuneration necessary and used solely to receive and transmit electronic prescription information, as provided in Section 11164 of the Health and Safety Code. Nonmonetary remuneration includes hardware, software, information technology, and training services for purposes of facilitating the electronic transmission of prescription information.~~ *to provide nonmonetary remuneration, in the form of hardware, software, or information technology and training services, necessary and used solely to receive and transmit electronic prescription information in accordance with the standards set forth in Section 1860D-4(e) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395w-104) in the following situations:*

(A) In the case of a hospital, by the hospital to members of its medical staff.

(B) In the case of a group medical practice, by the practice to prescribing health care professionals that are members of the practice.

(C) In the case of Medicare prescription drug plan sponsors or Medicare Advantage organizations, by the sponsor or organization to pharmacists and pharmacies participating in the network of the sponsor or organization and to prescribing health care professionals.

(2) The exceptions set forth in this subdivision are adopted to conform state law with the provisions of Section 1860D-4(e)(6) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395w-104) and are limited to drugs covered under Part D of the federal Medicare Program that are prescribed to Part D eligible individuals (42 U.S.C. Sec. 1395w-101).

(3) The exceptions set forth in this subdivision shall not be operative until the regulations required to be adopted by the Secretary of the United States Department of Health and Human Services, pursuant to Section 1860D-4(e) of the Medicare

Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395W-104) are effective.

~~"Health~~

(e) "Health care facility" means a general acute care hospital, acute psychiatric hospital, skilled nursing facility, intermediate care facility, and any other health facility licensed by the State Department of Health Services under Chapter 2 (commencing with Section 1250) of Division 2 of the Health and Safety Code.

~~A~~

(f) A violation of this section is a public offense and is punishable upon a first conviction by imprisonment in the county jail for not more than one year, or by imprisonment in the state prison, or by a fine not exceeding fifty thousand dollars ($50,000), or by both that imprisonment and fine. A second or subsequent conviction is punishable by imprisonment in the state prison or by imprisonment in the state prison and a fine of fifty thousand dollars ($50,000).

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 225 **VERSION: AMENDED APRIL 7, 2005**

AUTHOR: NEGRETE MCLEOD **SPONSOR: L.A. CARE HEALTH PLAN**

RECOMMENDED POSITION: SUPPORT IF AMENDED

SUBJECT: ELECTRONIC PRESCRIPTION INFORMATION.

Existing Law:

1) The Federal Medicare Prescription Drug, Improvement and Modernization Act of 2003 ("DIMA") establishing a "safe harbor" for certain health care providers and administrators to exchange "nonmonetary remuneration" under certain limitations to stimulate the use of e-prescribing.

2) State law relative to insurance fraud makes it a crime for healing arts practitioners to receive money or other consideration for, or to engage in various related activities with respect to, the referral of patients, clients, or customers to any person, with certain exceptions (B&P 650)

This Bill:

1) Allows health care professionals to receive nonmonetary remuneration, in the form of hardware, software, or information technology and training services, necessary and used solely to receive and transmit electronic prescription information in accordance with the standards set forth in Section 1860D-4(e) of the Medicare Prescription Drug, Improvement and Modernization Act of 2003 (42 U.S.C. Sec. 1395w-104), in the following circumstances:

a. In the case of a hospital, by the hospital to members of its medical staff;

b. In the case of a group medical practice, by the practice to prescribing health care professionals that are members of the practice; and,

c. In the case of Medicare prescription drug plan sponsors or Medicare Advantage organizations, by the sponsor or organization to pharmacists and pharmacies participating in the network of the sponsor or organization and to prescribing health care professionals.

2) Limits the application of this bill to drugs covered under Part D of the federal Medicare Program that are prescribed to Part D eligible individuals.

3) Makes this bill operative only when the regulations adopted by the Secretary of the U.S. Department of Health and Human Services become effective.

Comment:

1) Author's Intent. The author's intent is to conform state law to applicable federal provisions so the advances in e-prescribing can take place in California without violating existing state laws. The author believes AB 225 is an initial step towards expanded e-health, and improvements in the quality and efficiency of health care in California, in a fashion consistent with national policies and goals.

2) Consumer Gain? An argument can be made that getting hardware and software for e-prescriptions writing into the hands of prescribers will benefit consumers. Generally e-prescriptions have been thought of as a way to reduce prescription errors, but recent studies have shown that that while e-prescriptions have reduced errors, they are not error free. Consequently, increasing the number of health care professionals and pharmacies capable of writing and processing e-prescriptions should be in the consumers' interests.

AB 225 may have the unintended consequence of restricting consumer choice. Business and Professions Code section 4170 gives patients the option of obtaining a prescription for a pharmacy of their choice. If prescribers and pharmacies are given hardware and software to facilitate e-prescriptions, a health care professional that has the option of writing e-prescriptions may direct patients to specific pharmacies that have the ability to process these prescriptions with preprogrammed connections to specific pharmacies. These pharmacies may not be the ones a consumer would choose in the absence of the prescriber influence. Additionally, software compatibility (prescribers' and pharmacys') may restrict choice to specific pharmacies again limiting a patient's freedom of choice. Pharmacies that are equipped to process e-prescriptions are likely to see a financial gain if this measure is enacted.

Who stands to gain the most if AB 225 is enacted? Prescribers, consumers, or pharmacies?

3) Federal Legislation. U.S. Senators Frist and Clinton have introduced the "Health Technology to Enhance Quality Act of 2005." The Act would implement health information technology standards that would guide the design and operation of interoperable health information systems. The legislation would codify the Office of National Coordinator for Information Technology and establishs standards for the electronic exchange of health information. The measure would also establish a narrow statutory safe harbor from the federal "Stark" self-referral and Antikickback laws for standard compliant hardware, software and support services. The safe harbor would apply to physicians and other health care providers as long as these tools are used to exchange health information as part of a system designed to improve health care quality and safety, reduce medical errors, reduce health care costs, improve care coordination, simplify administrative processes, and promote transparency and competition. Lastly the measure would direct the Secretary of Health and Human Services to conduct a study of privacy laws and practices to determine how the variation among such state laws and practices may impact the electronic exchange of health information among states, between states and the federal government, and among private entities.

4) Amendment. The prescriber, prior to the electronic transmitting of a prescription, offers to transmit the prescription to a pharmacy of the patient's choice.

5) Support & Opposition.

Support:
L.A. Care Health Plan (sponsor)
AARP California
California Association of Health Plans
California Association of Physician Groups
California Medical Association
First 5 LA
Healthcare Information and Management Systems Society, So. Cal
Health-e-LA Coalition
Local Health Plans of California
Los Angeles County Medical Association
Rite-Aid
San Francisco Health Plan

Opposition: None on file.

6) History.

2005	
June 14	In committee: Set, first hearing. Hearing canceled at the request of author.
June 7	In committee: Hearing postponed by committee.
May 5	Referred to Com. on B., P. & E.D.
Apr. 18	In Senate. Read first time. To Com. on RLS. for assignment.
Apr. 18	Read third time, passed, and to Senate. (Ayes 75. Noes 0. Page 980.)
Apr. 14	Read second time. To third reading.
Apr. 13	From committee: Do pass. (Ayes 14. Noes 0.) (April 12).
Apr. 11	Re-referred to Com. on HEALTH.
Apr. 7	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Apr. 5	In committee: Set, first hearing. Hearing canceled at the request of author.
Feb. 15	Referred to Com. on HEALTH.
Feb. 4	From printer. May be heard in committee March 6.
Feb. 3	Read first time. To print.

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AMENDED IN SENATE JUNE 21, 2005
AMENDED IN ASSEMBLY MAY 9, 2005
AMENDED IN ASSEMBLY APRIL 13, 2005
AMENDED IN ASSEMBLY APRIL 5, 2005
CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 657

Introduced by Assembly Member Karnette
(Coauthor: Assembly Member Mountjoy)

February 17, 2005

An act to amend Section 4076 of, and to add Section 4079 to, the Business and Professions Code, relating to pharmacies.

LEGISLATIVE COUNSEL'S DIGEST

AB 657, as amended, Karnette. Pharmacies: prescription containers: labels.

Existing law, the Pharmacy Law makes the California State Board of Pharmacy responsible for the regulation of the practice of pharmacy. Existing law generally makes it a misdemeanor to knowingly violate the Pharmacy Law.

The Pharmacy Law prohibits a pharmacist from dispensing a prescription except in a container that meets the requirements of state and federal law and is correctly labeled with, among other things, the condition for which the drug was prescribed if requested by the patient and if the condition is indicated on the prescription.

This bill would eliminate the requirement of the labeling requirement pertaining to the condition for which the drug was prescribed, and would instead require the container to be labeled with the intended purpose, as defined, of the drug, as set forth on the

prescription, and would require that the purpose be listed on the prescription.

The bill would, *except for veterinarians,* require a person who is authorized to write or issue a prescription to ask the patient or his or her authorized representative whether to indicate the intended purpose of the prescription on the prescription's label.

Because the bill would specify additional requirements under the Pharmacy Law, the violation of which is a crime, it would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 4076 of the Business and Professions Code is amended to read:

4076. (a) A pharmacist shall not dispense any prescription except in a container that meets the requirements of state and federal law and is correctly labeled with all of the following:

(1) Except where the prescriber or the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052 orders otherwise, either the manufacturer's trade name of the drug or the generic name and the name of the manufacturer. Commonly used abbreviations may be used. Preparations containing two or more active ingredients may be identified by the manufacturer's trade name or the commonly used name or the principal active ingredients.

(2) The directions for the use of the drug.
(3) The name of the patient or patients.
(4) The name of the prescriber or, if applicable, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.
(5) The date of issue.
(6) The name and address of the pharmacy, and prescription number or other means of identifying the prescription.
(7) The strength of the drug or drugs dispensed.
(8) The quantity of the drug or drugs dispensed.
(9) The expiration date of the effectiveness of the drug dispensed.
(10) The intended purpose of the drug or drugs, if indicated on the prescription. As used in this section, "purpose" means a concise description of the symptom or symptoms that the drug is, or drugs are, intended to treat.
(11) (A) Commencing January 1, 2006, the physical description of the dispensed medication, including its color, shape, and any identification code that appears on the tablets or capsules, except as follows:
(i) Prescriptions dispensed by a veterinarian.
(ii) An exemption from the requirements of this paragraph shall be granted to a new drug for the first 120 days that the drug is on the market and for the 90 days during which the national reference file has no description on file.
(iii) Dispensed medications for which no physical description exists in any commercially available database.
(B) This paragraph applies to outpatient pharmacies only.
(C) The information required by this paragraph may be printed on an auxiliary label that is affixed to the prescription container.
(D) This paragraph shall not become operative if the board, prior to January 1, 2006, adopts regulations that mandate the same labeling requirements set forth in this paragraph.

(b) If a pharmacist dispenses a prescribed drug by means of a unit dose medication system, as defined by administrative regulation, for a patient in a skilled nursing, intermediate care, or other health care facility, the requirements of this section will be satisfied if the unit dose medication system contains the aforementioned information or the information is otherwise readily available at the time of drug administration.

(c) If a pharmacist dispenses a dangerous drug or device in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include on individual unit dose containers for a specific patient, the name of the certified nurse-midwife who functions pursuant to a standardized procedure or protocol described in Section 2746.51, the nurse practitioner who functions pursuant to a standardized procedure described in Section 2836.1, or protocol, the physician assistant who functions pursuant to Section 3502.1, or the pharmacist who functions pursuant to a policy, procedure, or protocol pursuant to either subparagraph (D) of paragraph (4) of, or clause (iv) of subparagraph (A) of paragraph (5) of, subdivision (a) of Section 4052.

(d) If a pharmacist dispenses a prescription drug for use in a facility licensed pursuant to Section 1250 of the Health and Safety Code, it is not necessary to include the information required in paragraph (11) of subdivision (a) when the prescription drug is administered to a patient by a person licensed under the Medical Practice Act (Chapter 5 (commencing with Section 2000)), the Nursing Practice Act (Chapter 6 (commencing with Section 2700)), or the Vocational Nursing Practice Act (Chapter 6.5 (commencing with Section 2840)), who is acting within his or her scope of practice.

SEC. 2. Section 4079 is added to the Business and Professions Code, to read:

4079. A person described in paragraph (2) of subdivision (a) of Section 4040 shall ask the patient or the patient's authorized representative, if the patient is either incapacitated or a minor who can not provide informed consent, whether to indicate the intended purpose of the prescription on the prescription's label. *This section does not apply to prescriptions dispensed by veterinarians.*

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 657 **VERSION: AMENDED JUNE 21, 2005**

AUTHOR: KARNETTE **SPONSOR: SENIOR LEGISLATORS**

RECOMMENDED POSITION: OPPOSE

SUBJECT: PHARMACIES: PRESCRIPTION CONTAINERS: LABELS

Existing Law:

Prohibits a pharmacist from dispensing a prescription except in a container that meets the requirements of state and federal law and is correctly labeled. (B&P 4076(a))

If requested by the patient, a label may list the condition for which the drug was prescribed. (B&P 4076(a)(10))

This Bill:

Revises the prescription labeling requirement to require a container to be labeled with, among other things, the "intended purpose" for which the drug was prescribed, if the intended purpose is listed on the prescription. (B&P 4076(a)(10) Amended)

The revised prescription labeling requirement would not apply to prescriptions dispensed by veterinarians. (B&P 4079 Amended)

Comment:

1) Author's Intent. The author intends to increase patient compliance and reduce confusion with prescribed drug therapy.

2) Confusion. Many prescription drugs have more than one use or purpose. A number of people, particularly seniors, have unexpired prescription drugs in their medicine cabinets, and do not know the intended use for the drug because it is omitted from the label. Many patients are unaware of their right to request that the prescription label contain information about the drug's purpose.

Including the purpose for the prescription drug on the prescription label may 1) reduce the number of telephone calls to doctors and pharmacists requesting information about the purpose of a prescription; 2) provide a check system between the doctor writing the prescription and the pharmacist filling the prescription; and 3) reduce medication error.

3) Other Legislation. A version of AB 288 (AB 2125 Levine 2004) was introduced in 2004. The author pulled the bill before its first committee hearing.

AB 288 (Mountjoy 2005) Pharmacies Prescription Containers Labels, a bill very similar to AB 657 has been introduced this session. AB 288 would require prescription labels to contain the

"condition" for which a drug is prescribed unless the patient receiving the drug request the information be omitted. Assemblyman Mounthjoy pulled AB 288 before it could be heard in its first committee hearing.

4) History.

2005

June 27	In committee: Hearing postponed by committee.
June 21	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on B., P. & E.D.
June 14	In committee: Hearing postponed by committee.
June 2	Referred to Com. on B., P. & E.D.
May 19	In Senate. Read first time. To Com. on RLS. for assignment.
May 19	Read third time, passed, and to Senate. (Ayes 42. Noes 30. Page 1608.)
May 10	Read second time. To third reading.
May 9	Read second time and amended. Ordered returned to second reading.
May 5	From committee: Amend, and do pass as amended. (Ayes 12. Noes 5.) (May 4).
Apr. 27	In committee: Hearing postponed by committee.
Apr. 20	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 8. Noes 4.) (April 19).
Apr. 5	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Mar. 7	Referred to Coms. on HEALTH and B. & P.
Feb. 18	From printer. May be heard in committee March 20.
Feb. 17	Read first time. To print.

ASSEMBLY BILL No. 896

Introduced by Assembly Member Matthews

February 18, 2005

An act to amend Section 4052.1 of, and to add Section 1209.2 to, the Business and Professions Code, relating to pharmacists.

LEGISLATIVE COUNSEL'S DIGEST

AB 896, as introduced, Matthews. Clinical laboratories.

Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacists by the California State Board of Pharmacy. Under that law, a pharmacist is authorized to perform skin puncture in the course of routine patient assessment procedures or specified clinical laboratory testing. Existing law providing for the licensure and regulation of clinical laboratories and their personnel by the State Department of Health Services, requires that these functions be performed under the supervision of a laboratory director, as defined. Under existing law, a violation of the provisions regulating clinical laboratories and their personnel is a crime.

This bill would authorize a pharmacist to serve as a laboratory director of a clinical laboratory that provides routine patient assessment procedures, as defined, under specified conditions.

Because a pharmacist acting in this capacity without satisfying the designated criteria would violate the provisions regulating clinical laboratories, and would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 1209.2 is added to the Business and Professions Code, to read:

1209.2. Notwithstanding any other provision of law, a pharmacist may serve as a laboratory director, as described in Section 1209, in a clinical laboratory that provides routine patient assessment procedures, as defined in Section 4052.1, if both of the following conditions are satisfied:

(a) The pharmacist has completed a training program on the duties and responsibilities of a laboratory director for a clinical laboratory performing tests classified as "waived" under CLIA.

(b) The clinical laboratory possesses a certificate of waiver under CLIA.

SEC. 2. Section 4052.1 of the Business and Professions Code is amended to read:

4052.1. *(a)* Notwithstanding Section 2038 or any other provision of law, a pharmacist may perform skin puncture in the course of performing routine patient assessment procedures or in the course of performing any procedure authorized under Section 1206.5. For purposes of this section, "routine patient assessment procedures" means *either of the following*: ~~(a) procedures~~

(1) Procedures that a patient could, with or without a prescription, perform for himself or herself~~, or (b) clinical~~.

(2) Clinical laboratory tests that are classified as waived pursuant to the federal Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. Sec. 263a) and the regulations adopted thereunder by the federal ~~Health Care Financing Administration~~ *Centers for Medicare and Medicaid Services*, as authorized by paragraph (11) of subdivision (a) of Section 1206.5. ~~A~~

(b) A pharmacist performing these functions shall report the results obtained from a test to the patient and any physician designated by the patient. ~~Any~~

(c) A pharmacist who performs the service authorized by this section shall not be in violation of Section 2052.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY

BILL ANALYSIS

BILL NUMBER: AB 896 **VERSION: INTRODUCED**

AUTHOR: MATTHEWS **SPONSOR: CPHA**

RECOMMENDED POSITION: SUPPORT

SUBJECT: CLINICAL LABORATORIES

Existing Law:

1) Permits a physician or a person licensed as a clinical laboratory director to act as a clinical laboratory director. (B&P 1209)

2) Requires clinical laboratory directors to meet the requirements established by the federal Clinical Laboratory Improvement Amendments (CLIA). (B&P 1209)

3) Requires the clinical laboratory director to be responsible for the operation of the clinical laboratory including:

- administration
- selecting and supervising laboratory procedures
- reporting laboratory test results
- ensuring compliance with CLIA
- supervising laboratory personnel

4) Defines "routine patient assessment procedures" as a procedures that a patient could, with or without a prescription, perform for himself or herself, or clinical laboratory tests that are classified as waived pursuant to CLIA. (B&P 4052.1)

This Bill:

1) Permits a pharmacist to serve as a laboratory director when:

a. The laboratory is only conducting laboratory tests that a pharmacist may perform under existing law.

b. The pharmacist has completed a training program on the duties and responsibilities of a laboratory director for a clinical laboratory performing tests classified as "waived" under CLIA.

c. The clinical laboratory possesses a certificate of waiver under CLIA.

(B&P 1209.2 Added)

2) The tests that can be preformed are:

a. Procedures that a patient could, with or without a prescription, perform for himself or herself.

b. Clinical laboratory tests that are classified as waived under CLIA.

3) Requires the pharmacist performing laboratory tests to report the results to both the patient and any physician specified by the patient. (B&P 4052.1 Amended)

Comment:

1) Author's Intent. The bill was introduced to permit pharmacists to perform waived tests in a pharmacy without an outside laboratory director. The sponsor further indicates, that by permitting pharmacists to perform waived tests in a pharmacy, patients will have better access to tests required to appropriately manage their drug therapy.

The author has also introduced AB 1370 this session, which would accomplish the same goal as AB 896. After some reflection, the author has decided to drop AB 1370 and put efforts into AB 896.

2) CLIA?. Prior to 1988, less that 10% of all clinical laboratories were required to meet quality standards. Approximately 12,000 hospitals and independent laboratories were regulated under the Clinical Laboratory Improvement Act of 1967 (CLIA '67) and the Medicare and Medicaid programs. Congressional hearings revealed serious deficiencies in quality in physician office laboratories and in Pap smear testing. Studies have demonstrated that laboratories meeting minimum personnel and quality requirements perform better than those that do not. CLIA '88 was passed to provide assurance to the public that access to safe, accurate laboratory testing is available.

Currently, under the Clinical Laboratory Improvement Amendments of 1988 (CLIA '88), all 150,000 clinical laboratories, including physician office laboratories, are regulated to ensure the quality of test results.

The CLIA '88 regulation unified and replaced past standards with the single set of requirements that apply to laboratory testing of human specimens. Standards for laboratory personnel, quality control and quality assurance are based on test complexity and potential harm to the patient.

3) Complexity. Determining which CLIA '88 standards apply to a test depends upon the level of complexity of that test. Three categories of testing complexity have been defined under CLIA '88. They are waived, moderate and high. One reason the tests are placed into categories is to reduce the burden of regulation for those laboratories performing tests for which a low probability of an erroneous result exists. For example, there are no personnel or inspection requirement for the waived category of testing. In addition, 75% of all tests falls within the moderate complexity category which permits an individual with only a high school degree and appropriate training to perform these tests.

4) California CLIA. CLIA permits a state with stricter clinical laboratory standards to obtain an exemption from federal regulation (and fees) if the lab tests and personnel that would be subject to CLIA are regulated by that state's clinical lab law.

Prior to the enactment of the CLIA, California already had an extensive administrative scheme for regulating clinical labs and lab personnel. However, that state law was not, in all respects, equal to or greater in regulatory oversight coverage to CLIA. Consequently, in 1995 the Legislature enacted SB 113 to bring California's clinical lab law into compliance with all of CLIA's requirements so that California could obtain a waiver from CLIA and continue to regulate its clinical labs at the state level.

One of the key components of CLIA and state clinical lab law was the requirement that clinical labs be overseen by a lab director who would be responsible for the quality control of the testing and the competency and training of the personnel who were conducting the tests. Besides a licensed physician, California law permits other persons, a licensed bioanalyst or a clinical chemist to qualify as a lab director.

5) Legislative History. AB 896 is similar to AB 1460 (Nation 2003), Laboratory Directors. The board supported this bill. AB 1460 died in its first committee hearing.

6) Related Legislation. AB 1370 (Matthews 2005), Clinical Laboratory Directors: Pharmacists, would amend B&P 1209, to redefine a laboratory director to include a pharmacist if the clinical laboratory test or examination is a routine patient assessment procedure. The author's office has stated that the author plans to drop this bill since it would accomplish the same thing as AB 896.

7) History.

2005	
Apr. 12	In committee: Hearing postponed by committee.
Mar. 29	In committee: Set, first hearing. Hearing canceled at the request of author.
Mar. 7	Referred to Coms. on B. & P. and HEALTH
Feb. 20	From printer. May be heard in committee March 22.
Feb. 18	Read first time. To print.

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AMENDED IN SENATE APRIL 18, 2005

SENATE BILL No. 152

Introduced by Senator Speier

February 7, 2005

~~An act to add Section 4051.1 to the Business and Professions Code, relating to pharmacy.~~ *An act to add, repeal, and add Section 11100.02 of the Health and Safety Code, relating to controlled substances.*

LEGISLATIVE COUNSEL'S DIGEST

SB 152, as amended, Speier. Pseudoephedrine.

Under existing law, a retailer who makes an over-the-counter retail sale of pseudoephedrine is generally subject to a 3-package per transaction limitation or 9-gram per transaction limitation. Any violation of this requirement is a crime.

This bill would impose additional requirements on the sale by a pharmacist or retail distributor, as defined, of a product, except as specified, containing any amount of pseudoephedrine or its salts or isomers or the salts of isomers of pseudoephedrine. The bill would, effective June 1, 2006, require the purchaser of the product to present a government-issued photo identification and would require that a retail distributor's staff complete certain training before selling the product. The bill would add to these requirements, effective January 1, 2008, a provision that the pharmacist and retail distributor maintain a record of the sales of the product and limit sales to a single purchaser to 3 packages or 9 grams within a 30-day period.

Because the bill would make a violation of these provisions a crime, it would impose a state-mandated local program.

~~Existing law, the Pharmacy Law, provides for the licensure and regulation of pharmacies and pharmacists by the California State Board of Pharmacy. That law authorizes a pharmacist to furnish and~~

~~dispense prescription drugs. A knowing violation of the Pharmacy Law is a misdemeanor.~~

~~This bill would prohibit, subject to specified exceptions, the furnishing of a product containing pseudoephedrine by other than a pharmacist or pharmacy technician in a pharmacy. The bill would limit the amount of the product that a person could acquire in a 30-day period and would impose requirements on acquisition.~~

~~Because the bill would specify additional requirements under the Pharmacy Law, the violation of which is a crime, it would impose a state-mandated local program.~~

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

~~SECTION 1. Section 4051.1 is added to the Business and Professions Code, to read:~~

SECTION 1. Section 11100.02 is added to the Health and Safety Code, to read:

11100.02. (a) A pharmacist and a retail distributor, as defined in paragraph (5) of subdivision (h) of Section 11100, shall store products containing any amount of pseudoephedrine or the salts, isomers, or salts of isomers of pseudoephedrine in a locked area.

(b) A pharmacy and a retail distributor shall not sell a product described in subdivision (a) to a purchaser unless the purchaser presents a valid, current identification that contains a photo of himself or herself and that was issued by a governmental agency.

(c) No staff member of a retail distributor may sell a product described in subdivision (a) unless the staff member has received training in both of the following subjects:

(1) Identification of pseudoephedrine products.

(2) Usage of pseudoephedrine in manufacturing methamphetamine.

(d) This section shall not apply to either of the following:

(1) A compound, mixture, or preparation of pseudoephedrine that is in liquid, liquid capsule, or gel capsule form if pseudoephedrine is not the only active ingredient. "Gel capsule" means any soft gelatin, liquid-filled capsule that contains a liquid suspension in a matrix of glycerine, polyethylene glycol, propylene glycol, and other liquid substances. Regardless of the product manufacturer's labeling, a gelatin covered solid is not a gel capsule for purposes of this subdivision.

(2) A pediatric liquid, as defined in paragraph (4) of subdivision (h) of Section 11100.

(e) A first violation of this provision is a misdemeanor. A person who has previously been convicted of a violation of this section shall, upon a subsequent conviction thereof, be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars ($10,000), or by both the fine and imprisonment.

(f) This section shall become operative on June 1, 2006, and shall remain in effect only until January 1, 2008, and as of that date is repealed, unless a later enacted statute, that is enacted before January 1, 2008, deletes or extends that date.

SEC. 2. Section 11100.02 is added to the Health and Safety Code, to read:

11100.02. (a) A pharmacist and a retail distributor, as defined in paragraph (5) of subdivision (h) of Section 11100, shall store products containing any amount of pseudoephedrine or the salts, isomers, or salts of isomers of pseudoephedrine in a locked area.

(b) A pharmacy and a retail distributor shall not sell a product described in subdivision (a) to a purchaser unless the purchaser presents a valid, current identification that contains a photo of himself or herself and that was issued by a governmental agency.

(c) (1) Before selling a product described in subdivision (a) to a purchaser, the pharmacist or retail distributor shall record the following information:

(A) The date of purchase.

(B) The name and address of the purchaser.

(C) The number of the identification presented by the purchaser.

(D) The name and amount of the product, as described in subdivision(a), that was purchased.

(2) The pharmacy and retail distributor shall maintain the record described in paragraph (1) for at least three years from the product's date of purchase in an electronic format approved by the Attorney General.

(d) (1) A pharmacist or a retail distributor shall not sell more than three packages or more than nine grams of the product described in subdivision (a) within any 30-day period to a single purchaser.

(2) A pharmacist and a retail distributor shall develop a system that notifies the pharmacist or retail distributor that the limitation described in paragraph (1) has been reached.

(e) No staff member of a retail distributor may sell a product described in subdivision (a) unless the staff member has received training in both of the following subjects:

(1) Identification of pseudoephedrine products.

(2) Usage of pseudoephedrine in manufacturing methamphetamine.

(f) This section shall not apply to either of the following:

(1) A compound, mixture, or preparation of pseudoephedrine that is in liquid, liquid capsule, or gel capsule form if pseudoephedrine is not the only active ingredient. "Gel capsule" means any soft gelatin, liquid-filled capsule that contains a liquid suspension in a matrix of glycerine, polyethylene glycol, propylene glycol, and other liquid substances. Regardless of the product manufacturer's labeling, a gelatin covered solid is not a gel capsule for purposes of this subdivision.

(2) A pediatric liquid, as defined in paragraph (4) of subdivision (h) of Section 11100.

(g) A first violation of this provision is a misdemeanor. A person who has previously been convicted of a violation of this section shall, upon a subsequent conviction thereof, be punished by imprisonment in a county jail not exceeding one year, by a fine not exceeding ten thousand dollars ($10,000), or by both the fine and imprisonment.

(h) This section shall become operative on January 1, 2008.

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school

district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

~~4051.1. (a) A product containing any amount of pseudoephedrine or the salts, isomers, or salts of isomers of pseudoephedrine shall be furnished only by a pharmacist or pharmacy technician in a pharmacy.~~

~~(b) Notwithstanding Section 11100 of the Health and Safety Code, no person shall purchase, receive, or otherwise acquire more than nine grams of the product described in subdivision (a) within any 30-day period. Before purchasing, receiving, or otherwise acquiring a product described in subdivision (a), a person shall produce a valid California driver's license or other valid identification containing a photograph of the person and showing his or her date of birth. The person shall sign a written document, as specified by the Attorney General, indicating the date of the purchase, receipt, or acquisition and the amount of the product involved in the transaction.~~

~~(c) The pharmacist shall store the product described in subdivision (a) in a locked area within the view of the pharmacist. The pharmacist and all persons with access to the locked storage area shall prevent the theft or diversion of the product.~~

~~(d) (1) This section shall not apply to a compound, mixture, or preparation of pseudoephedrine that is in liquid, liquid capsule, or gel capsule form if pseudoephedrine is not the only active ingredient. "Gel capsule" means any soft gelatin, liquid-filled capsule that contains a liquid suspension in a matrix of glycerine, polyethylene glycol, propylene glycol, and other liquid substances. "Active ingredient" includes the matrix found in liquid capsules. Regardless of the product manufacturer's labeling, a gelatin-covered solid is a gel capsule for purposes of this subdivision.~~

~~(2) The exception in paragraph (1) shall not apply to a liquid preparation that is discovered in an illegal laboratory, that is associated with an illegal laboratory, or that is any form other~~

~~than one manufactured and sold by a manufacturer for medicinal purposes.~~

~~(c) This section does not apply to a substance furnished pursuant to a valid prescription.~~

~~SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.~~

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 152 **VERSION: AMENDED APRIL 18, 2005**

AUTHOR: SPEIER **SPONSOR: SPEIER**

RECOMMENDED POSITION: OPPOSE

SUBJECT: PSEUDOEPHEDRINE

Existing Law:

1) It unlawful for a manufacturer, wholesaler, retailer, or other person to sell, transfer or furnish pseudoephedrine to a person under 18 years of age. (H&S 11100(g)(1))

2) It unlawful for a person under 18 years of age to possess pseudoephedrine. (H&S 11100(g)(2))

3) It is unlawful for a retail distributor to sell in a single transaction more than three packages of a product that he or she knows to contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or knowingly sell more than nine grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, other than pediatric liquids. (H&S 11100(g)(3))

This Bill:

1) Deletes B&P 405.1 provisions of the previous versions of the bill and replaces them with new H&S 11100.02 provisions.

2) Adds H&S 11100.02 Section 1 and states Section 1 will become operative on June 1, 2006, and will remain in effect only until January 1, 2008; Section 2 would become operative January 1, 2008.

Section 1

a. Requires a pharmacist and a retail distributor to store products containing any amount of pseudoephedrine or the salts, isomers, or salts of isomers of pseudoephedrine [product] in a locked area.

b. Prohibits a pharmacy and a retail distributor from selling a product to a purchaser unless the purchaser presents a valid, current identification that contains a photo of himself or herself and that was issued by a governmental agency.

c. Requires staff members of a retail distributor to receive training in the following areas before they are permitted to sell product:

    i. Identification of pseudoephedrine products.

    ii. Usage of pseudoephedrine in manufacturing methamphetamine.

d. Makes a first violation of the provisions of the bill a misdemeanor and subsequent violations punishable by imprisonment in a county jail not exceeding one year, a fine not exceeding ten thousand dollars ($10,000), or by both the fine and imprisonment.

e. Exempts the following products from the provisions of the bill: a compound, mixture, or preparation of pseudoephedrine that is in liquid, liquid capsule, or gel capsule form if pseudoephedrine is not the only active ingredient; a pediatric liquid.

3) Adds H&S 11100.02 Section 2 and states Section 2 shall become operative on January 1, 2008.

4) Repeats the requirements in Section 1 and adds the following requirements:

a. Requires a pharmacist and a retail distributor, to record the following information prior selling a product:

i. The date of purchase.

ii. The name and address of the purchaser.

iii. The number of the identification presented by the purchaser.

iv. The name and amount of the product that is purchased.

b. Requires a pharmacy and retail distributor to maintain the record for at least three years from the product's date of purchase in an electronic format approved by the AG.

c. Restricts the sale of product to no more than three packages or more than nine grams of the product within any 30-day period to a single purchaser.

d. Requires a pharmacist and a retail distributor to develop a system that notifies the pharmacist or retail distributor when a purchaser's limit has been reached.

(H&S 11100.02 Added)

Comment:

1) Author's Intent. The author is seeking to limit the supply of pseudoephedrine available for illegal methamphetamine (meth) production, while making the product reasonably accessible for legitimate use.

2) Enforcement. The April 18th version of the bill takes the provisions of the bill out of the Pharmacy Law and places them in the H&S Code. Consequently, the board would not be responsible for enforcing the measure.

3) Retail Chains' Voluntary Efforts. In an effort to combat illegal methamphetamine production, the following major drug retailers have voluntarily agreed to move all single ingredient pseudoephedrine products behind the pharmacy counter: Albertsons, CVS, Longs Drugs, Kmart, Rite Aid, Shopko, Target, Walgreens, and Wal-mart. Additionally, the National Association of Chain Drug Stores, which represents more than 36,000 pharmacies, supports federal legislation (S 103) to reduce access to pseudoephedrine products, including requiring the sale of pseudoephedrine products behind the pharmacy counter by a licensed pharmacist or pharmacy personnel.

4) State Legislation. AB 283 (Koretz), Pseudoephedrine: retail sale, is similar to SB 152 in its attempt to restrict the sale of pseudoephedrine for illegal uses. AB 283 would limit access to ephedrine and pseudoephedrine products by requiring 1) the products to be placed in a locked cabinet, and 2) a retail employee check the identification of a purchaser and report specified information about purchases to the DOJ. AB 283 would place these provisions in H&S 11100.01.

Development Committee on June 27, 2005; the measure was granted reconsideration, but has not been rescheduled for a hearing.

AB 162 (Runner 1999, C. 978) made it a misdemeanor for any retail distributor to sell more than 3 packages of a product that contain ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, or more than 9 grams of ephedrine, pseudoephedrine, norpseudoephedrine, or phenylpropanolamine, in a single transaction.

5) Federal Legislation. In January 2005, S103 and HR 314, the Combat Meth Act of 2005, were introduced in Congress. Each of these measures contains provisions similar to those in SB 283. Both Federal measures are waiting to be heard in committee.

6) History.

2005

May 2	Reconsideration granted.
Apr. 25	Set, final hearing. Failed passage in committee. (Ayes 3. Noes 3. Page 768.)
Apr. 18	From committee with author's amendments. Read second time.Amended. Re-referred to committee.
Apr. 11	Set, second hearing. Hearing canceled at the request of author. Set for hearing April 25.
Apr. 4	Set, first hearing. Hearing canceled at the request of author. Set for hearing April 18.
Mar. 23	Set for hearing April 11.
Feb. 24	To Com. on B., P. & E.D.
Feb. 8	From print. May be acted upon on or after March 10.
Feb. 7	Introduced. Read first time. To Com. on RLS. for assignment. To print.

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AMENDED IN ASSEMBLY JUNE 15, 2005

AMENDED IN SENATE MAY 4, 2005

AMENDED IN SENATE APRIL 12, 2005

AMENDED IN SENATE APRIL 4, 2005

SENATE BILL No. 401

Introduced by Senator Ortiz

February 17, 2005

An act to amend Section 56.05 of the Civil Code, relating to medical information.

LEGISLATIVE COUNSEL'S DIGEST

SB 401, as amended, Ortiz. Medical information: pharmacies: marketing.

Existing law prohibits a provider of health care, a health care service plan, contractor, or corporation and its subsidiaries and affiliates from intentionally sharing, selling, or otherwise using any medical information, as defined, for any purpose not necessary to provide health care services to a patient, except as expressly authorized by the patient, enrollee, or subscriber, as specified, or as otherwise required or authorized by law. Violations of these provisions are subject to a civil action for compensatory and punitive damages, and, if a violation results in economic loss or personal injury to a patient, it is punishable as a misdemeanor. Existing law provides that this prohibition also applies to the marketing of medical information, as defined, excluding from that definition, for these purposes, communications for which the communicator does not receive remuneration from a 3rd party or for specified descriptive purposes, or that are tailored to the circumstances of a particular individual, as specified.

This bill would further provide that marketing includes a written communication that is provided by a pharmacy to a patient about a different drug or treatment than that being dispensed by the pharmacy and that is paid for, or sponsored by, a manufacturer, labeler, or distributor of prescription drugs, except as specified. Because a violation thereof may be punishable as a misdemeanor, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Section 56.05 of the Civil Code is amended to read:

56.05. For purposes of this part:

(a) "Authorization" means permission granted in accordance with Section 56.11 or 56.21 for the disclosure of medical information.

(b) "Authorized recipient" means any person who is authorized to receive medical information pursuant to Section 56.10 or 56.20.

(c) "Contractor" means any person or entity that is a medical group, independent practice association, pharmaceutical benefits manager, or a medical service organization and is not a health care service plan or provider of health care. "Contractor" does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code or pharmaceutical benefits managers licensed pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(d) "Health care service plan" means any entity regulated pursuant to the Knox-Keene Health Care Service Plan Act of 1975 (Chapter 2.2 (commencing with Section 1340) of Division 2 of the Health and Safety Code).

(e) "Licensed health care professional" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code, the Osteopathic Initiative Act or the Chiropractic Initiative Act, or Division 2.5 (commencing with Section 1797) of the Health and Safety Code.

(f) (1) "Marketing" means to make a communication about a product or service that encourages recipients of the communication to purchase or use the product or service.

(2) "Marketing" does not include any of the following:

(A) Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication.

(B) Communications made to current enrollees solely for the purpose of describing a provider's participation in an existing health care provider network or health plan network of a Knox-Keene licensed health plan to which the enrollees already subscribe; communications made to current enrollees solely for the purpose of describing if, and the extent to which, a product or service, or payment for a product or service, is provided by a provider, contractor, or plan or included in a plan of benefits of a Knox-Keene licensed health plan to which the enrollees already subscribe; or communications made to plan enrollees describing the availability of more cost-effective pharmaceuticals.

(C) Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about treatment options, and otherwise maintain the individual's adherence to a prescribed course of medical treatment, as provided in Section 1399.901 of the Health and Safety Code, for a chronic and seriously debilitating or life-threatening condition as defined in subdivisions (d) and (e) of Section 1367.21 of the Health and Safety Code, if the health care provider, contractor, or health plan receives direct or indirect remuneration, including, but not limited to, gifts, fees, payments, subsidies, or other economic benefits, from a third party for making the communication, if all of the following apply:

(i) The individual receiving the communication is notified in the communication in typeface no smaller than 14-point type of

the fact that the provider, contractor, or health plan has been remunerated and the source of the remuneration.

(ii) The individual is provided the opportunity to opt out of receiving future remunerated communications.

(iii) The communication contains instructions in typeface no smaller than 14-point type describing how the individual can opt out of receiving further communications by calling a toll-free telephone number of the health care provider, contractor, or health plan making the remunerated communications. No further communication may be made to an individual who has opted out after 30 calendar days from the date the individual makes the opt out request.

(3) ~~"Marketing"~~ *Notwithstanding any other provision of law, "marketing"* includes a written communication that is provided to a pharmacy patient by a pharmacist or by pharmacy personnel, in conjunction with the dispensing of a prescription drug or prescribed treatment therapy, that includes the trade name or commercial slogan for any prescription drug, prescribed treatment therapy, or over-the-counter medication other than the prescription drug or prescribed treatment therapy being dispensed, if the communication is paid for or sponsored, directly or indirectly, by a manufacturer, labeler, or distributor of prescription drugs. This paragraph shall not apply when a trade name or commercial slogan for a prescription drug, prescribed treatment therapy, or over-the-counter medication is included in a written communication for the sole purpose of ~~identifying a potential adverse drug interaction with the prescription drug or prescribed treatment therapy being dispensed.~~ *providing information about drug interactions, reported or potential adverse events, or any other information necessary to ensure the health and safety of the patient, or is part of a package insert that has been approved by the federal Food and Drug Administration to be distributed together with a prescription drug.*

(g) "Medical information" means any individually identifiable information, in electronic or physical form, in possession of or derived from a provider of health care, health care service plan, pharmaceutical company, or contractor regarding a patient's medical history, mental or physical condition, or treatment. "Individually identifiable" means that the medical information includes or contains any element of personal identifying

information sufficient to allow identification of the individual, such as the patient's name, address, electronic mail address, telephone number, or social security number, or other information that, alone or in combination with other publicly available information, reveals the individual's identity.

(h) "Patient" means any natural person, whether or not still living, who received health care services from a provider of health care and to whom medical information pertains.

(i) "Pharmaceutical company" means any company or business, or an agent or representative thereof, that manufactures, sells, or distributes pharmaceuticals, medications, or prescription drugs. "Pharmaceutical company" does not include a pharmaceutical benefits manager, as included in subdivision (c), or a provider of health care.

(j) "Provider of health care" means any person licensed or certified pursuant to Division 2 (commencing with Section 500) of the Business and Professions Code; any person licensed pursuant to the Osteopathic Initiative Act or the Chiropractic Initiative Act; any person certified pursuant to Division 2.5 (commencing with Section 1797) of the Health and Safety Code; any clinic, health dispensary, or health facility licensed pursuant to Division 2 (commencing with Section 1200) of the Health and Safety Code. "Provider of health care" does not include insurance institutions as defined in subdivision (k) of Section 791.02 of the Insurance Code.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 401 **VERSION: AMENDED JUNE 15, 2005**

AUTHOR: ORTIZ **SPONSOR: CA. PUBLIC INTEREST RESEARCH GROUP**

RECOMMENDED POSITION: NONE

SUBJECT: MEDICAL INFORMATION: PHARMACIES: MARKETING

Existing Law:

1) Defines marketing as "communication about a product or service that encourages recipients of the communication to purchase or use the product or service."

2) Excludes the following from the definition of marketing:

a. Communications made orally or in writing for which the communicator does not receive direct or indirect remuneration from a third party for making the communication.

b. Communications made to current enrollees solely for the purpose of describing a provider's participation in an existing health care provider network or health plan network of a Knox-Keene licensed health plan to which the enrollees already subscribe

c. Communications that are tailored to the circumstances of a particular individual to educate or advise the individual about treatment options, and otherwise maintain the individual's adherence to a prescribed course of medical treatment for a chronic and seriously debilitating or life-threatening condition, if the health care provider, contractor, or health plan receives direct or indirect remuneration from a third party for making the communication, if all of the following apply:

i. The individual receiving the communication is notified in the communication in typeface no smaller than 14-point type of the fact that the provider, contractor, or health plan has been remunerated and the source of the remuneration.

ii. The individual is provided the opportunity to opt out of receiving future remunerated communications.

iii. The communication contains instructions in typeface no smaller than 14-point type describing how the individual can opt out of receiving further communications by calling a toll-free number of the health care provider, contractor, or health plan making the remunerated communications.

(Civil Code 56.05)

This Bill:

Defines "marketing" to include a written communication that is provided to a pharmacy patient by a pharmacist or by pharmacy personnel, in conjunction with the dispensing of a prescription drug or prescribed treatment therapy, that includes the trade name or commercial slogan for any prescription drug, prescribed treatment therapy, or over-the-counter medication other than the prescription drug or prescribed treatment therapy being dispensed, if the:

1. The communication describes includes the name of, or describes biochemical, pharmacological, or other scientific or health information for, any other drug or treatment other than the drug or treatment being dispensed; and
2. The communication is paid for or sponsored, directly or indirectly, by a manufacturer, labeler, or distributor of prescription drugs.

Specifies that this definition does not apply when 1) a trade name or commercial slogan for a prescription drug, prescribed treatment therapy, or 2) over-the-counter medication is included in a written communication for the sole purpose of providing information about drug interactions, reported or potential adverse events, or any other information necessary to ensure the health and safety of the patient, or is part of a package insert that has been approved by the federal Food and Drug Administration to be distributed together with a prescription drug.

(Civil Code 56.05 Amended)

Comment:

1) Author's Intent. The author's intent is to close a loophole that she sees in the law that allows drug manufacturers to distribute biased written information to patients through pharmacists during face-to-face drug consultations. An example would be an pharmacist giving a patient an advertisement, during the face to face consultation, that list other possible drugs that could be taken for the same condition.

2) Background. AB 715 (Chan, Chapter 562, Statutes of 2003), sought to prohibit marketing practices where a health care provider or entity was paid to market a third party's product or service to a patient, using that patient's medical information. While the bill protected consumer privacy, it did not completely deal with issues surrounding third party marketing to consumers. The question arises, does permitting drug companies to pay for advertising or the production of fact sheets used by pharmacists in consultations with patients benefit or harm the consumer?

AB 746 (Mathews, 2003) was proposed as "clean-up" legislation to AB 715. AB 746 would have clarified that pharmacists had the right to provide patient pamphlets with drug manufacture advertising or messages that informed patients of about the drug they were receiving. Pharmacists argued that including advertisements helped pay for the costs of producing the pamphlets and that prohibiting advertising would result in patients receiving less information about the drug they are taking. AB 746 died in the Senate.

Likewise, SB 401 is also being proposed as "clean-up" legislation to AB 715, but unlike AB 746, it takes the position that marketing information from drug manufacturers during face-to-face interaction is bad for the consumer and should therefore be prohibited. Supporters of the measure argue that information from pharmacists should be free from bias and information from drug manufacturers may confuse patients and contradict the information they receive from their doctor.

3) Previous Legislation.

AB 715 (Chan, Chapter 562, Statutes of 2003) Personal Information.

AB 746 (2003) Medical Information: Pharmacies, Marketing; this measure died in the Senate.

4) Support & Opposition

Support: California Public Interest Research Group (sponsor)
California Alliance for Retired Americans
California Labor Federation
Consumers Union

Opposition: The Body
CA Pharmacists Association
CA Retailers Association
Catalina Health Resource; Kaiser Permanente
Nat'l Association of Chain Drug Stores
Nat'l Consumers League
Nat'l Council on Patient Information and Education
Novartis Pharmaceuticals
Pharmaceutical Research and Manufacturers of America
Rite Aid

5) History.

2005

June 28	Set, first hearing. Hearing canceled at the request of author.
June 15	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
June 13	To Coms. on HEALTH and JUD.
May 26	In Assembly. Read first time. Held at Desk.
May 26	Read third time. Passed. (Ayes 23. Noes 13. Page 1190.) To Assembly.
May 25	Read second time. To third reading.
May 24	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
May 16	Set for hearing May 23.
May 4	Read second time. Amended. Re-referred to Com. on APPR.
May 3	From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 5. Noes 2. Page 801.)
Apr. 14	Set for hearing April 26.
Apr. 12	Read second time. Amended. Re-referred to Com. on JUD.
Apr. 11	From committee: Do pass as amended, but first amend, and re-refer to Com. on JUD. (Ayes 8. Noes 3. Page 498.)
Apr. 4	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 16	Set for hearing April 6.
Feb. 24	To Coms. on HEALTH and JUD.
Feb. 18	From print. May be acted upon on or after March 20.
Feb. 17	Introduced. Read first time. To Com. on RLS. for assignment. To print.

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AMENDED IN SENATE MARCH 29, 2005

SENATE BILL No. 592

Introduced by Senator Aanestad

February 18, 2005

An act to add Article 7.6 (commencing with Section 4128) to Chapter 9 of Division 2 of the Business and Professions Code, relating to pharmacy technicians.

LEGISLATIVE COUNSEL'S DIGEST

SB 592, as amended, Aanestad. Acute care hospitals: inpatient pharmacy technician services.

Existing law, the Pharmacy Law, provides for the regulation of the practice of pharmacy by the California State Board of Pharmacy, in the Department of Consumer Affairs. Existing law authorizes a registered pharmacy technician to assist in the performance of pharmacy related duties under the supervision of a licensed pharmacist. A violation of the Pharmacy Law is a crime.

This bill would authorize a general acute care hospital to implement a program utilizing specially trained pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for certain patients, if specified requirements are met. *The bill would require a hospital that operates this program to keep a list of all qualified pharmacy technicians available for board inspection and to keep all required data in the hospital for at least 3 years.*

Because a failure to meet the training *and other* requirements in this bill would be a crime, the bill would impose a state-mandated local program.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state.

Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Pharmacists have emerged as critical members of a medical team by providing services such as patient education, drug therapy monitoring, and pharmacokinetic consultations. Pharmacists often work side by side with physicians and nurses, and participate in medical rounds. Pharmacists play an integral role in ensuring a safe medication use process. Through interpretation, evaluation, and clarification of orders, pharmacists ensure the absence of drug allergies, interactions, duplications, and the optimal selection of dose, dosage form, frequency, route, and duration of therapy.

(b) There currently exists a shortage of pharmacists in the state, and this shortage has the potential to cause harm to patients because hospitals lack sufficient staffing to fully take advantage of clinical pharmacy programs that have been shown to reduce the number of medication errors in hospitals and improve patient outcomes.

(c) Studies authorized by the California State Board of Pharmacy, and conducted under the direction of the University of California, San Francisco, at major California hospitals, have established that certain nondiscretionary functions currently performed by pharmacists in the hospital setting can safely be performed by properly trained pharmacy technicians. Specifically, allowing properly trained pharmacy technicians to check certain tasks performed by other pharmacy technicians is a safe and efficient use of staff, and frees pharmacists to provide the more important and skilled clinical pharmacy services that are critical to quality patient care and the reduction of medication errors.

(d) Pharmacists are substantially over-qualified for performing these nondiscretionary inpatient checking functions, and current rules that require pharmacists to perform these functions unnecessarily limit hospitals in their capacity to fully provide patients with clinical pharmacy services.

(e) It is the intent of the Legislature in enacting this act that pharmacists remain responsible for pharmacy operations. Nothing in these provisions should be interpreted to eliminate or minimize the role of pharmacists in directly supervising pharmacy technicians and pharmacy operations. It is the further intent of the Legislature that hospitals take advantage of the efficiencies created by these provisions by using properly trained pharmacy technicians for certain nondiscretionary checking functions and more completely utilize the training and skills of their pharmacist staff to implement and expand clinical pharmacy programs at their facilities.

~~SECTION 1.~~

SEC. 2. Article 7.6 (commencing with Section 4128) is added to Chapter 9 of Division 2 of the Business and Professions Code, to read:

Article 7.6. Inpatient Pharmacy Technician Services

~~4128. Notwithstanding any other provision of this chapter or any other provision of law, a general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, may implement and operate a program utilizing specially trained pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed by a licensed pharmacist. A hospital implementing and operating a program pursuant to this section shall meet all of the following requirements:~~

~~(a) The hospital shall conduct a special training program for technicians who perform the checking function that provides the technicians with the same training that a pharmacist would be provided with under paragraph (1) of subdivision (b) of Section 4052.~~

~~(b) The hospital shall conduct a continuous quality improvement program.~~

~~(c) The hospital shall establish and maintain a program utilizing pharmacists to provide clinical services, as described in Section 4052.~~

~~(d) The hospital shall have a current, nonprovisional, nonconditional accreditation from the Joint Commission on the Accreditation of Healthcare Organizations or another nationally recognized accrediting organization.~~

4128. (a) Notwithstanding any other provision of law, a general acute care hospital, as defined in subdivision (a) of Section 1250 of the Health and Safety Code, may implement and operate a program utilizing specially trained pharmacy technicians to check the work of other pharmacy technicians in connection with the filling of floor and ward stock and unit dose distribution systems for patients admitted to the hospital whose orders have previously been reviewed by a licensed pharmacist. The hospital may implement and operate this type of a program if all of the following requirements are met:

(1) The hospital conducts a special training program for technicians who perform the checking function that satisfies the requirements of subdivision (b).

(2) The hospital conducts a continuous quality improvement program that, at a minimum, audits the performance of the specially trained pharmacy technicians at least every three months for the first year, and annually thereafter. A pharmacy technician whose audited accuracy rate falls below 99.8 percent shall not be permitted to check the work of other pharmacy technicians until he or she is requalified pursuant to paragraph (1).

(3) The hospital has a current nonprovisional, nonconditional accreditation from the Joint Commission on the Accreditation of Healthcare Organizations or another nationally recognized accrediting organization.

(4) The hospital pharmacy has been inspected by the board.

(5) The hospital establishes and maintains a program utilizing pharmacists to provide clinical services as described in Section 4052.

(b) The training program required by paragraph (1) of subdivision (a) shall include both didactic and practical

elements, and shall specify requirements to be completed prior to the technician commencing participation in the checking program.

(1) The didactic component of the training shall consist of at least four hours of education covering the following topics:

(A) Information required to be on the label of unit dose or extemporaneous packaging.

(B) Identification of expired or contaminated medications.

(C) The product characteristics that need to be checked for each drug dispensed from the pharmacy.

(D) Special packaging or handling requirements, including refrigeration for certain medications.

(E) Generic names for common name-brand medications.

(F) Recognition and identification of various dosage forms.

(G) Common medical abbreviations and symbols used in pharmacy.

(H) Basic mathematical principles used in pharmacy calculations, including conversions between and within metric, avoirdupois, and apothecary systems.

(2) The practical component of the training shall consist of at least two hours of supervised practice in which the trainee both observes proper checking procedures and performs proper checking procedures under the direct observation of the supervisor.

(c) The board may, by regulation, establish other rules for hospitals utilizing specially trained pharmacy technicians pursuant to this section.

(d) The board may order a hospital to cease activities authorized by this section at any time a hospital fails to satisfy the board that it is capable of continuing to meet the requirements of this section.

(e) Data and records required by this section shall be retained in each participating hospital for at least three years.

(f) Medication that has been placed in floor or ward stock or unit dose distribution systems pursuant to this section shall not be administered to a patient except by a licensed health care provider practicing within the scope of his or her license.

(g) Legal responsibility or liability for errors or omissions that occur as a result of a pharmacy technician checking another pharmacy technician's work pursuant to this section shall be

limited to the holder of the pharmacy permit and the pharmacist in charge.

4128.1. (a) Every hospital utilizing pharmacy technicians to check the work of other pharmacy technicians pursuant to Section 4128 shall maintain for inspection by the board a current list of all pharmacy technicians that have been qualified to perform checking functions.

(b) A pharmacy technician is not eligible to be qualified pursuant to this article unless he or she:

(1) Is currently certified by the Pharmacy Technician Certification Board.

(2) Is currently registered with the board as a pharmacy technician pursuant to Section 4202.

~~SEC. 2.~~

SEC. 3. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 592 **VERSION: AMENDED MARCH 29, 2005**

AUTHOR: AANESTEAD **SPONSOR: CALIFORNIA SOCIETY OF HEALTH SYSTEMS PHARMACISTS**

RECOMMENDED POSITION: SUPPORT

SUBJECT: TECHNICIAN CHECKING TECHNICIAN

Existing Law:

1) Requires pharmacy technicians to be licensed by the board. (B&P 4115)

2) Permits pharmacy technicians to perform packaging, manipulative, repetitive, or other nondiscretionary tasks under the direct supervision of a pharmacist as follows:

a. Removing drugs from stock.
b. Counting, pouring, or mixing pharmaceuticals
c. Placing product in a container.
d. Affixing a label or labels to the container.
e. Packaging and repackaging.

(CCR 1793.2)

3) Requires pharmacy technicians to possess a high school education and fulfill one of the following requirements to be licensed:

a. Associate degree in pharmacy technology.
b. Complete a training course approved by the board.
c. Is eligible to take the board examination for licensure as a pharmacist.

(CCR 1793.5, 1793.6)

This Bill:

1) Permits general acute care hospitals to employ specially trained pharmacy technicians to check the work of other pharmacy technicians (TCT) filling floor stock, ward stock, and unit dose cassettes. (B&P 4128 Added)

2) Requires hospitals implementing TCT to do the following:

a. Conduct ongoing training for technicians.
b. Conduct continuous quality improvement programs to audit the performance of technicians in TCT programs.
c. Remove any technician in TCT programs whose accuracy rate falls below 99.8 percent.

d. Possess a current accreditation from the Joint Commission on the Accreditation of Health Care Organizations (JCAHO), or another nationally recognized accrediting organization.

e. Be inspected by the Board of Pharmacy.

f. Establish a program using pharmacists to provide clinical services.

(B&P 4128 Added)

3) Requires training for pharmacy technicians to include both didactic and practical elements, and to be completed prior to technicians commencing participation in the checking program.

a. The didactic component of the training shall consist of at least four hours of education covering the following topics:

i. Information required to be on the label of unit dose or extemporaneous packaging.

ii. Identification of expired or contaminated medications.

iii. The product characteristics that need to be checked for each drug dispensed from the pharmacy.

iv. Special packaging or handling requirements, including refrigeration for certain medications.

v. Generic names for common name-brand medications.

vi. Recognition and identification of various dosage forms.

vii. Common medical abbreviations and symbols used in pharmacy.

viii. Basic mathematical principles used in pharmacy calculations, including conversions between and within metric, avoirdupois, and apothecary systems.

b. The practical component of the training shall consist of at least two hours of supervised practice in which the trainee both observes proper checking procedures and performs proper checking procedures under the direct observation of the supervisor.

(B&P 4128 Added)

4) Permits the board to adopt other rules related to TCT. (B&P 4128 Added)

5) Permits the board to order a hospital to cease a TCT program. (B&P 4128 Added)

6) Requires that data and records for TCT programs be retained for three years.

(B&P 4128 Added)

7) Specifies that legal responsibility for errors in the TCT process is that of the pharmacy and the pharmacist-in-charge. (B&P 4128 Added)

8) Requires hospitals to have a list of technicians in TCT programs available for inspection by the board. (B&P 4128.1Added)

9) Requires pharmacy technicians participating in TCT programs by certified by the Pharmacy Technician Certification Board. (B&P 4128.1 Added)

Comment:

1) Author's Intent. The author is seeking to apply the model TCT program evaluated in a study project at Cedars Sinai Medical Center and Long Beach Memorial Hospital. The results of that study were published in the American Journal of Health System Pharmacy, June 2002, and found the practice to be safe and that TCT allowed staff pharmacists to spend more time addressing clinical issues with patients and prescribers.

2) Legislative History. In 2003 the author introduced SB 393, a bill similar to SB 592. SB 393 was opposed by the United Food and Commercial Union (labor), consequently the measure failed to make it beyond its second committee hearing.

The sponsor of SB 592 is engaging labor in discussions in hopes labor will either support or remain neutral on the bill.

3) Board History. At its October 2001 meeting, the board voted to support legislation that would allow a pharmacy technician to check another pharmacy technician filling unit-dose cassettes in an inpatient hospital pharmacy. At that meeting the board expressed a desire for TCT programs to emulate those operated by Cedars-Sinai and Long Beach Memorial under the board waiver.

In April 2003, the board voted to support SB 393.

At the January 2004 board meeting the board approved a two-year pilot program at UCSF / Cedars to allow TCT to continue while documentation of duties preformed by pharmacists continue. This pilot program will end in 2006.

4) Amended on March 29, 2005. The amendments 1) detail training for pharmacy technicians who participate in the program, and 2) specified requirements for the quality improvement program required by the measurer. This version of the bill is similar to AB 393, as amended on July 16, 2003.

5) History.

2005	
June 14	Set, first hearing. Failed passage in committee. Reconsideration granted.
May 26	To Com. on HEALTH.
May 9	In Assembly. Read first time. Held at Desk.
May 9	Read third time. Passed. (Ayes 23. Noes 8. Page 972.) To Assembly.
May 3	Read second time. To third reading.
May 2	From committee: Be placed on second reading file pursuant to Senate Rule 28.8.
Apr. 21	Set for hearing May 2.
Apr. 18	From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 4. Noes 1. Page 625.) Re-referred to Com. on APPR.
Mar. 30	Set for hearing April 18.
Mar. 29	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Mar. 3	To Com. on B., P. & E.D.
Feb. 19	From print. May be acted upon on or after March 21.
Feb. 18	Introduced. Read first time. To Com. on RLS. for assignment. To print.

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AMENDED IN SENATE JUNE 23, 2005

AMENDED IN ASSEMBLY MAY 26, 2005

AMENDED IN ASSEMBLY APRIL 18, 2005

AMENDED IN ASSEMBLY APRIL 7, 2005

AMENDED IN ASSEMBLY FEBRUARY 11, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 71

Introduced by Assembly Members Chan and Frommer (Coauthors: Assembly Members Bass, Cohn, Evans, Gordon, Koretz, and Pavley)

January 3, 2005

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to pharmaceuticals.

LEGISLATIVE COUNSEL'S DIGEST

AB 71, as amended, Chan. Pharmaceuticals: adverse drug reactions: Office of California Drug Safety Watch.

Existing law, the Sherman Food, Drug, and Cosmetic Law, regulates the packaging, labeling, and advertising of food, drugs, and cosmetics, under the administration of the State Department of Health Services.

This bill would establish the Office of California Drug Safety Watch within the department and would require the office, among other duties, to establish a central repository of information about the safety and effectiveness of prescription drugs ~~frequently advertised on television,~~ *that belong to classes of drugs for which there have been*

recently published reports of safety concerns, that have been frequently advertised directly to consumers, and for which there are recently published systematically reviewed evidence-based research that includes research on side effects and safety issues. The bill would require the office to disseminate information to health care professionals and consumers through an Internet Web site~~,~~ *and* to request assistance from the University of California and California State University~~, and to rely on systematically reviewed evidence-based research~~.

This bill would require the department to impose a fee on any manufacturer of drugs sold in the state, in an amount based on the drug manufacturer's market share of the total amount of drugs sold in the state.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Since 1997, when the United States Food and Drug Administration (FDA) allowed drug manufacturers to advertise directly to consumers, the amount spent on advertising has risen dramatically.

(b) According to the United States General Accounting Office (GAO) report, the pharmaceutical industry spent $2.7 billion in 2001 on direct-to-consumer advertising. A December 6, 2004, New York Times report states that such spending has reached $3.8 billion.

(c) According to the same GAO report, while overall spending on drug promotion was less than spending on research and development ($19.1 billion versus $30.3 billion), spending on direct-to-consumer advertising is increasing at a faster rate than overall drug promotion spending or spending on research and development. Between 1997 and 2001, the increase in direct-to-consumer advertising was 145 percent compared to a 59 percent increase for research and development.

(d) Although the FDA is responsible for postmarket surveillance of prescription drugs, numerous concerns have been raised about the adequacy of these efforts.

(e) An unpublished internal FDA study from 2002 revealed that 18 percent of FDA scientists reported being pressured to approve a new drug "despite reservations about the safety, efficacy or quality of the drug."

(f) A 1999 FDA survey and a Kaiser Family Foundation survey both found that more than 50 million people respond to drug advertisements by asking their doctor whether the advertised medications might work for them. At the same time, both surveys showed that almost 60 percent of consumers found the side-effect warnings in these advertisements to be inadequate.

(g) Pressure to get new drugs to market, combined with the vast amount of drug marketing undertaken by manufacturers, make it difficult to address a threat once it is identified. Recent studies linking the use of popular, widely promoted prescription drugs to serious public health concerns point to the need for greater oversight to protect the public.

(h) Drugs that are frequently advertised to consumers present special safety concerns because direct-to-consumer advertising is likely to minimize potential side effects and safety concerns and because advertised drugs are likely to be highly utilized by Californians.

~~(h)~~

(i) Californians do not have a reliable central repository of information about prescription drug safety and effectiveness.

~~(i)~~

(j) California physicians and other prescribers could benefit from a reliable central repository of information about prescription drug safety and effectiveness.

~~(j)~~

(k) Various nationally respected sources of clinical information are available as sources for a central respository of information about prescription drug safety and effectiveness.

~~(k)~~

(l) Safer and more effective prescription drugs within a class may also be among the less expensive prescription drugs within that class, meaning that a reliable central repository of information about prescription drug safety and effectiveness would create opportunities for prescription drug cost savings.

SEC. 2. Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. Office of California Drug Safety Watch

111657. (a) There is hereby established in the State Department of Health Services the Office of California Drug Safety Watch, which shall do all of the following, to provide Californians with information on the safety and effectiveness of prescription drugs:

(1) Establish a central repository of information about the safety and effectiveness of prescription drugs that are ~~frequently advertised on television.~~ *selected pursuant to subdivision (b). The repository shall not include information about any therapeutic class of drugs that is used primarily to treat mental illness.*

(2) Disseminate information to California health care professionals and consumers through an Internet Web site that shall include links to other relevant Web-based information that has been professionally reviewed and approved. *The Internet Web site shall include the following statement: "Many factors enter into selecting the proper drug for individual patients. Before changing any medication, a patient shall consult with his or her treating physician or other prescriber."*

(3) Ensure that the dissemination of information is done in a culturally competent manner and addresses the differential impact of medications within a class based on gender, age, and ethnicity, when that information is available. *When there is no evidence supporting the differential impact of medication among various demographic groups, it shall be noted on the Internet Web site.*

~~(4) In selecting therapeutic classes of drugs about which to develop information, the office shall choose the four most frequently advertised classes of drugs for which there is recently published systemically reviewed evidence-based research.~~

~~(5) Request appropriate units of the University of California and the California State University to provide assistance.~~

~~(6) Rely on systematically reviewed evidence-based research.~~

~~(b) The office shall coordinate its activities with other state departments and agencies to avoid unnecessary duplication.~~

(b) In selecting therapeutic drugs about which to develop information, the office shall only include classes of drugs that have all of the following characteristics:

(1) Classes of drugs for which there have been recently published reports of safety concerns.

(2) Classes of drugs that have been frequently advertised directly to consumers.

(3) Classes of drugs for which there are recently published systemically reviewed evidence-based research that includes research on side effects and safety issues.

(c) The office shall request the appropriate units of the University of California and the California State University to provide assistance in implementing this article.

(d) The office shall coordinate its activities with other state departments and agencies to avoid unnecessary duplication.

(e) The office shall rely on systemically reviewed evidence-based research.

(f) The process that the office uses to identify relevant research and standards of clinical evidence shall be transparent and publicly available.

111657.1. For purposes of this article, the following terms have the following meanings:

~~(a) "Evidence-based research" means prescription drug research in which the drugs in question have been administered to experimental and control groups and the subsequent effect of the drugs has been observed through those groups.~~

(a) "Evidence-based research" means research that is based on clinical evidence, including therapeutic outcomes, and that uses a hierarchy of evidence to evaluate the reliability of the research. In well-conducted research, the hierarchy of evidence, from highest to lowest, is the system review of randomized clinical trials, individual randomized clinical trials, controlled trials, cohort studies, and case control studies.

(b) "Systematically reviewed" means review of evidence-based research that uses rigorous, unbiased methods to examine the similarities and differences of results across many individual research studies. The goal of a systematic review is to estimate the comparative effectiveness and safety of health care treatments. A systematic approach to reviewing the evidence

increases the reliability of the results, and the transparency of the procedures.

~~(c) "Most frequently advertised classes of drugs" means the therapeutic classes of drugs most frequently advertised on television for the six-month period prior to the date the office begins compiling the drug safety and effectiveness information required by this article. Frequently advertised classes of drugs shall not include any therapeutic class that is used primarily to treat mental illness.~~

111657.2. (a) There is hereby imposed, pursuant to this section, a fee on manufacturers of drugs sold in the state.

(b) (1) The specific fee to be assessed on a drug manufacturer shall be established by the State Department of Health Services, to the maximum extent practicable, on the basis of a drug manufacturer's market share of the total amount of drugs sold in the state.

(2) A fee shall not be assessed on a drug manufacturer that can demonstrate, as determined by the State Department of Health Services, that it does not manufacture drugs that have the characteristics described in subdivision (b) of Section 111657.

(c) The fee shall be assessed and collected annually by the State Board of Equalization in accordance with Part 22 (commencing with Section 43001) of Division 2 of the Revenue and Taxation Code. The fees collected shall be deposited in the Drug Safety Watch Fund, which is hereby established in the State Treasury. Moneys in the fund shall be expended, upon appropriation by the Legislature, for the purposes of this article, including the costs of the State Board of Equalization for collection and administration of fees. All interest earned on the moneys that have been deposited into the Drug Safety Watch Fund shall be retained in the fund.

(d) The fees collected pursuant to this section and the earnings therefrom shall be used solely for the purposes of implementing this article. The department shall not collect fees pursuant to this section in excess of the amount reasonably anticipated by the department to fully implement this article. The department shall not spend more than it collects from the fees, and the earnings thereon, in implementing this article.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 71 **VERSION: AMENDED APRIL 18, 2005**

AUTHOR: CHAN et. al. **SPONSOR: CHAN**

RECOMMENDED POSITION: NO POSITION

SUBJECT: PHARMACEUTICALS: ADVERSE DRUG REACTIONS: OFFICE OF CALIFORNIA DRUG SAFETY WATCH

Existing Law:

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establish the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufacturers about adverse drug reactions.

This Bill:

1) Establishes the Office of California Drug Safety Watch (office) within the Department of Health Services (DHS). (H&S 111657 Added)

2) Requires the office to do all of the following:

   a. Establish a central repository of information about the safety and effectiveness of prescription drugs.

   b. Disseminate information to health care professionals and consumers through an Internet Web site that would include links to other relevant web-based information that has been professionally reviewed and approved.

   c. Assure that the dissemination of information is done in a culturally competent manner.

   d. Request units of the University of California and the California State University to provide assistance.

   e. Rely on systematically reviewed evidence-based research.

   f. Give priority, when selecting therapeutic classes of drugs about which to develop information, to therapeutic classes that have one or all of the following characteristics:

      i. Classes of drugs in which there have been recently published reports of safety concerns.

      ii. Classes of drugs that have been advertised on television directly to consumers.

iii. Classes of drugs for which there is recently published systematically reviewed evidence-based research.

(H&S 111657 Added)

3) Authorize the office to review the formularies of all state-funded programs for their utilization of systematically reviewed evidence-based research. (H&S 111657 Added)

4) Requires the office to coordinate its activities with other state departments and agencies to avoid unnecessary duplication. (H&S 111657 Added)

5) Defines the following terms:

a. Evidence-based research to mean prescription drug research in which the drugs in question have been administered to experimental and control groups and the subsequent effect of the drugs has been observed through those groups.

b. Systematically reviewed to mean review of evidence-based research that uses rigorous, unbiased methods to examine the similarities and differences of results across many individual research studies. The goal of a systematic review is to estimate the comparative effectiveness and safety of healthcare treatments. A systematic approach to reviewing the evidence increases the reliability of the results, and the transparency of the procedures.

(H&S 111657.1 Added)

Comment:

1) Author's Intent. The author is concerned about drug safety and the perceived inability of the Federal government to take action to warn the public about potentially dangerous drugs.

2) Necessity for Bill? The intent of this legislation is to provide Californians with a reliable central repository of information about prescription drugs safety and effectiveness. This type of information is currently available through many sources, including the FDA, the Oregon Drug Effectiveness Review Project (ODERP), Consumers Union [Reports], and the AARP; all of which have Web sites that consumers and healthcare professionals can access for information. Given that reliable information is available, perhaps it would better and less costly for the Administration to direct DHS to establish a Web site with links to information on drug safety, rather than passing legislation that would require to DHS to establish a new program that essentially duplicates what is being done by other entities.

3) Drugmakers Plans for Voluntary Disclosure on the Internet. Reuters News reported on May 16, 2005 that the pharmaceutical industry plans to launch a global website in September, pooling information on ongoing and completed clinical trials, as it steps up a campaign to reassure patients about medicine safety. Drugmakers in the United States, Europe and Japan agreed in January on a voluntary code to publish detailed clinical trials data and said at the time they were exploring ways to make this information available through a single "window". The new portal will establish links to company websites and other commercial and government-sponsored websites containing information provided by firms. The voluntary code has the backing of major groups, including Pfizer Inc, GlaxoSmithKline Plc, Merck, AstraZeneca Plc, Novartis AG and Sanofi-Aventis SA. The move does not represent full disclosure, however, since early-stage phase I studies on healthy volunteers -- often the first sign a company has a good hunch about a new drug approach -- are exempt and there is no obligation to reveal the results of studies before a drug is approved. Companies also have up to a year to publish results. Drugmakers, already struggling to find enough new medicines to sustain historic growth rates, need to tread a fine line when deciding how much information to disclose about trials, according to industry analysts. While seeking to satisfy legislators, they are anxious to hold back anything that could give them a competitive advantage in an increasingly cut-throat industry.

4) Amended on April 18, 2005. The April 18th amendment deleted reference to the Oregon Drug Effectiveness Review Project from the legislative findings section of the bill. The OREDP is a three-year, $4.2 million collaboration of organizations that includes DHS and CalPERS. The project was formed to obtain the best available evidence on effectiveness and safety comparisons between drugs in the same class, and to apply the information to public policy and related activities.

5) Other Legislation. Two other bills dealing with drug safety and reporting requirements have been introduced this session.

SB 380 (Alquist) Drugs: Adverse Event Reporting, would require licensed health professionals and a health facilities to report serious adverse drug events that they observe to MedWatch, the FDA's drug safety information and adverse event reporting program. (MedWatch is a voluntary reporting program that allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use.)

SB 329 (Cedillo) California Prescription Drug Safety and Effectiveness Commission. This is a spot bill and may be amended for other purposes.

6) Federal Legislation. On May 4, 2005, Congressman Hinchey (D-NY) introduced H.R. 2090, the Food and Drug Administration Improvement Act of 2005. This bill would: 1) establish within the FDA a Center for Postmarket Drug Safety and Effectiveness to monitor all approved drugs as well as all advertisements and promotions associated with those products; 2) prohibit the FDA from collecting fees paid by companies it regulates and instead, deposit those funds into the general fund of the Treasury; 3) empower the FDA with the authority to mandate that companies conduct post-marketing studies of FDA-approved drugs; and 4) enable the FDA to mandate changes to labels of FDA-approved products if a new risk is discovered. HR 2090 has been referred to the House Committee on Health.

7) History.

2005	
April 27	In committee: Set, first hearing. Referred to APPR. suspense file.
Apr. 19	Re-referred to Com. on APPR.
Apr. 18	Read second time and amended.
Apr. 14	From committee: Amend, do pass as amended, and re-refer to Com. on APPR. (Ayes 9. Noes 4.) (April 12).
Apr. 11	Re-referred to Com. on HEALTH.
Apr. 7	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Feb. 15	Re-referred to Com. on HEALTH.
Feb. 11	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Com. on HEALTH.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

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AMENDED IN ASSEMBLY MAY 26, 2005

AMENDED IN ASSEMBLY APRIL 4, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 72

Introduced by Assembly Members Frommer and Chan (Coauthors: Assembly Members Bass, Evans, Gordon, Koretz, Nava, Pavley, and Salinas)

January 3, 2005

An act to add Chapter 9 (commencing with Section 119500) to Part 15 of Division 104 of the Health and Safety Code, relating to prescription drug trials.

LEGISLATIVE COUNSEL'S DIGEST

AB 72, as amended, Frommer. Prescription drugs: clinical trials.

Existing law regulates the labeling, sale, and use of prescription drugs and devices.

This bill would establish the Patient Safety and Drug Review Transparency Act in order to ~~assure~~ *ensure* that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers. The bill would prohibit an institutional review board with responsibility for ensuring the protection of the rights, safety, and well-being of human subjects involved in clinical trials of prescription drugs from approving any clinical trial related to a prescription drug unless the sponsor certifies in writing that it (1) will register the clinical trial, no later than 21 days after ~~it begins~~ *its approval by the institutional review board*, with a government sponsored and public clinical trial registry, (2) will publish the results of the study, and (3) has complied with the registry and publication

requirements for any prior ~~study~~ *clinical trial* that was approved by the board.

~~This bill would prohibit the board from approving any study related to a prescription drug if the sponsor failed during a prior study that was approved by the board to comply with the above requirements. Prior to approval, the bill would require the board to review whether the sponsor, in prior approved studies, actually complied with those requirements.~~

The bill would provide that any sponsor who does not comply with the requirements it certified in writing is liable for a civil penalty of $1,000 per violation. The bill would authorize the Attorney General, a district attorney, or city attorney to bring an action against a sponsor to ~~recover civil penalties~~ *enforce compliance with its requirements*.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. Chapter 9 (commencing with Section 119500) is added to Part 15 of Division 104 of the Health and Safety Code, to read:

CHAPTER 9. ~~INFORMATION REQUIRED FOR DRUG STUDIES~~ *PATIENT SAFETY AND DRUG REVIEW TRANSPARENCY*

119500. (a) This chapter may be referred to as the "Patient Safety and Drug Review Transparency Act."

(b) The purpose of this act is to ~~assure~~ *ensure* that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers. Making information about drug trials and their results available in a national, publicly accessible database will improve the safety of human subjects and provide all citizens of this state with complete safety information about the prescription drugs they take.

(c) For purposes of this chapter, the following terms have the following meanings:

(1) "Clinical trial" means a *Phase 2, 3, or 4* clinical investigation as defined by the federal Food and Drug Administration ~~that involves any experiment~~ to test the safety or efficacy of a drug or biological product with one or more human

subjects and is intended to be submitted to, or held for inspection by, the federal Food and Drug Administration as part of an application for a research or marketing permit.

(2) "Clinical trial registry" means a publicly available ~~databank~~ *database* established by the National Library of Medicine pursuant to 42 U.S.C. Section 282 (j).

(3) "Institutional review board" means an independent body constituted of medical, scientific, and nonscientific members, whose responsibility is to ensure the protection of the rights, safety, and well-being of human subjects involved in clinical trials of prescription drugs by, among other things, reviewing, approving, and providing continuing review of trial protocol and the methods and material to be used in obtaining and documenting informed consent of the trial subjects. *The institutional review board is constituted under Subtitle A (commencing with Section 46.101) of Part 46 of Title 45 of the Code of Federal Regulations, to review and monitor research involving human subjects.*

(4) "Sponsor" means the manufacturer, or if the manufacturer provides no monetary support for the trial, the person who provides the majority of monetary support, or, where the majority funder is a state or federal agency, the principal investigator.

~~(d) An institutional review board shall not approve any clinical trial related to a prescription drug unless the sponsor certifies in writing that it has done or will do all of the following:~~

(d) A sponsor of a clinical investigation shall certify to the relevant institutional review board and to the Attorney General that the sponsor has done or will do all of the following:

(1) Register the clinical trial, no later than 21 days after ~~it begins, by providing information necessary for publication in a government sponsored~~ *approval of the clinical trial by the institutional review board, by providing information necessary for publication in a government-sponsored* and public clinical trial registry in the manner required by regulations or other guidance established by the National Library of Medicine or the United States Secretary of Health and Human Services.

(2) Publish the ~~results of the study by providing the results of the study for publication~~ *summary results of the trial, whether positive or negative,* in a government sponsored and public clinical trial registry, in a manner required by regulations or other

guidance established by the National Library of Medicine or the United States Secretary of Health and Human Services, *in a peer-reviewed medical journal,* or in another publicly accessible database.

(3) Complied with the provisions of paragraphs (1) and (2) for any prior ~~study~~ *clinical trial* that was approved by the board pursuant to this chapter.

~~(c) An institutional review board shall not approve any study related to a prescription drug if the sponsor failed during a prior study that was approved by the board pursuant to this chapter to comply with the requirements it certified in writing under subdivision (d). Prior to approval, the board shall review whether the sponsor, in prior studies approved pursuant to this chapter, actually complied with those requirements.~~

~~(f) Any sponsor who does not comply with the requirements it certified in writing under subdivision (d) shall be liable for a civil penalty of one thousand dollars ($1,000) per violation payable to the general fund of the entity bringing the action. Each day a sponsor is in violation shall be considered a separate violation. The Attorney General, a district attorney, or city attorney may bring an action against a sponsor to recover civil penalties for not complying with the requirements the sponsor certified in writing under subdivision (d).~~

(e) Any sponsor who does not comply with the requirements of this chapter within 30 days after receipt of written notice from the Attorney General, a district attorney, or a city attorney shall be liable for a civil penalty of one thousand dollars ($1,000) per violation payable to the general fund of the entity bringing the action. Each day a sponsor remains in violation of this chapter after the conclusion of the 30-day period shall be considered a separate violation. The Attorney General, a district attorney, or a city attorney may bring an action against a sponsor to enforce compliance with the requirements of this chapter.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 72 **VERSION: AMENDED MAY 26, 2005**

AUTHOR: FROMMER et. al. **SPONSOR: FROMMER**

RECOMMENDED POSITION: NO POSITION

SUBJECT: CLINICAL TRIALS

Existing Law:

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establishes the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufacturers to report adverse drug reactions.

This Bill:

1) Establishes the Patient Safety and Drug Review Transparency Act.

2) Defines the terms: "Clinical trial", "Clinical trial registry", "Institutional review board", and "Sponsor."

3) Requires a sponsor of a clinical investigation to certify to the relevant institutional review board and to the Attorney General that the sponsor has done or will do all of the following:

a. Register the clinical trial, no later than 21 days after approval of the clinical trial by the institutional review board, by providing information necessary for publication in a government-sponsored and public clinical trial registry in the manner required by regulations or other guidance established by the National Library of Medicine or the United States Secretary of Health and Human Services.

b. Publish the summary results of the trial, whether positive or negative, in a government sponsored and public clinical trial registry, or other publicly accessible database.

c. Complied with the provisions of the measure for any prior clinical trial that was approved by the board.

5) Establishes a civil penalty of $1,000 per violation for any sponsor who does not comply with provisions of the bill. Each day a sponsor is in violation would be considered a separate violation.

(H&S 119500 Added)

Comment:

1) Author's Intent. The author's intent is to assure that information regarding clinical trials of prescription drugs is available to the public, physicians, and researchers.

2) History.

2005

June 2	Action rescinded and record expunged whereby the bill was read third time and whereby a final roll call vote was taken. To inactive file on motion of Assembly Member Frommer
May 27	Read second time. To third reading.
May 26	From committee: Amend, and do pass as amended. (Ayes 11. Noes 5.) (May 25). Read second time and amended. Ordered returned to second reading.
May 11	In committee: Set, first hearing. Referred to APPR. suspense file.
Apr. 13	From committee: Do pass, and re-refer to Com. on APPR. Re-referred. (Ayes 10. Noes 3.) (April 12).
Apr. 5	Re-referred to Com. on HEALTH.
Apr. 4	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Coms. on HEALTH and JUD.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

AMENDED IN SENATE JUNE 23, 2005

AMENDED IN ASSEMBLY APRIL 20, 2005

AMENDED IN ASSEMBLY APRIL 6, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 74

Introduced by Assembly Members Gordon and Frommer
(Coauthors: Assembly Members Chan, Chavez, Koretz, Laird, Matthews, Pavley, Ridley-Thomas, and Ruskin)
(Coauthor: Senator Alquist)

January 3, 2005

An act to add Article 5 (commencing with Section 110243) to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 74, as amended, Gordon. California Rx Prescription Drug Hotline.

Existing law, the Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of the State Department of Health Services.

This bill would require the department to establish the California Rx Prescription Drug Hotline, on or before July 1, 2006, to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices. The bill would establish a maximum cost per call to the hotline and require the hotline to provide specific information.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) Prescription drugs have become essential for ensuring the health of millions of Californians.

(b) Increased spending on prescription drugs is a significant driver of increases in overall health care costs.

(c) Rising out-of-pocket costs for prescription drugs are placing a growing burden on California consumers, as federal government statistics show that in 2002 the increase in consumers' out-of-pocket costs for prescription drugs was greater than the increase in out-of-pocket costs for all other health care expenditures.

(d) The price of brand name drugs is rising faster than the rate of inflation, with a recent study showing that the price of 30 drugs most frequently used by the elderly rose by over four times the rate of inflation in 2003 and that some drugs increased in price by 10 times the rate of inflation in that period.

(e) The rising cost of prescription drugs jeopardizes the health of seniors, the disabled, and other consumers who cannot afford the medication they need to stay healthy.

(f) California residents face a growing need for assistance in finding information about sources for prescription drugs at affordable prices.

SEC. 2. Article 5 (commencing with Section 110243) is added to Chapter 2 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 5. California Rx Precription Drug Hotline

110243. (a) The State Department of Health Services shall establish the California Rx Prescription Drug Hotline to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

(b) The department shall establish a low-cost 1-900 telephone number on or before July 1, 2006. Callers shall be provided with

information about options for obtaining prescription drugs at affordable prices. The cost per call to the hotline shall not exceed 50 cents ($0.50) and the hotline shall, at a minimum, provide information about all of the following:

~~(1) Prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program and the Medicare Prescription Drug Discount and Transitional Assistance Program.~~

~~(2)~~

(1) State programs that provide drugs at discounted prices for California residents.

~~(3)~~

(2) Federal programs that provide drugs at discounted prices for United States residents.

~~(4)~~

(3) Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals.

~~(5)~~

(4) Other informational resources as deemed appropriate by the department that help California residents to safely obtain prescription drugs at affordable prices, including, but not limited to, both of the following:

(A) Information regarding the availability of prescription drugs from Canada that are distributed from pharmacies licensed in that country and that meet standards and regulations prescribed by the state or federal government.

(B) Telephone numbers and *Internet* Web sites of health plans and health insurers regarding their prescription drug formularies.

~~(6)~~

(5) Price comparisons of at least 50 commonly prescribed brand name prescription drugs, including typical prices charged by all of the following:

(A) Licensed pharmacies in the state.

(B) Licensed pharmacies in other states.

(C) Pharmacies located in Canada that are licensed by that country and that meet standards prescribed by the state and federal government.

(c) The department shall ensure that the hotline established pursuant to this section is coordinated with and does not

duplicate other state-funded programs and services, including, but not limited to, programs such as the Health Insurance Counseling and Advocacy Program (HICAP) established pursuant to Chapter 7.5 (commencing with Section 9540) of Division 8.5 of the Welfare and Institutions Code, that provide information about prescription drug options and costs.

(d) Any information provided via the hotline shall first be approved by professional staff of the department.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 74 **VERSION: AMENDED June 23, 2005**

AUTHOR: GORDON **SPONSOR: GORDON**

RECOMMENDED POSITION:

SUBJECT: CALIFORNIA RX PRESCRIPTION DRUG HOTLINE

Existing Law:

The Sherman Food, Drug, and Cosmetic Law, provides for the regulation of the packaging, labeling, and advertising of food, drugs, devices, and cosmetics, under the administration of the California Department of Health Services (DHS). (H&S 109875)

This Bill:

1) Requires the DHS to establish the California Rx Prescription Drug Hotline (hotline) to provide information to consumers and health care providers about options for obtaining prescription drugs at affordable prices.

2) Requires DHS to establish a low-cost 1-900 telephone number on or before July 1, 2006 and to limit the cost per call to the hotline to no more than 50 cents per call. The hotline would provide the following information:

a. State programs that provide drugs at discounted prices for California residents.

b. Federal programs that provide drugs at discounted prices for United States residents.

c. Pharmaceutical manufacturer patient assistance programs that provide free or low-cost prescription drugs to qualifying individuals.

d. Information regarding the availability of prescription drugs from Canada that are distributed from pharmacies licensed in that country and that meet standards and regulations prescribed by the state or federal government.

e. Telephone numbers and Web sites of health plans and health insurers regarding their prescription drug formularies.

f. Price comparisons of at least 50 commonly prescribed brand name prescription drugs, including typical prices charged by 1) licensed pharmacies in the state, 2) licensed pharmacies in other states, and 3) pharmacies located in Canada that are licensed by that country and that meet standards prescribed by the state and federal government.

3) Requires that DHS ensure that the hotline is coordinated with and does not duplicate other state-funded programs and services , including, but not limited to, the Health Insurance Counseling and Advocacy Program (HICAP),, that provide information about prescription drug options and costs.

(H&S 1010243 Added)

Comment:

1) Author's Intent. The author's intent is to provide a one-stop-shop for information on how to obtain low priced prescription drugs. While much of this information is available on the Internet, the author is concerned that it's not getting to senior citizens, many of which who have never used a computer, let alone Internet.

As introduced, the measure would require DHS to establish a 1-900 telephone number for the program. The author is considering amending the bill to link the new program to an existing program and established 1-800 number. One option would be to link the program to the Health Insurance Counseling and Advocacy Program (HICAP), within California Department of Aging. HICAP assists individuals and families with Medicare problems and provides information on Medicare, Medicare supplement insurance, managed care, long-term care planning and health insurance.

2) Oversight. One of the many roles a pharmacist fills is acting as a second check for prescribers to insure that the medication a patient has been prescribed is the right medication for the patient's health condition, and that multiple medications will not adversely interact with each other to negatively effect a patient's health. As patients see specialist doctors for multiple health problems, the pharmacist's oversight role become increasingly more important, as any one doctor may not be aware of all the prescription drugs a patient is taking. Additionally, as patients seek lower cost drugs from more than one source (mail order, Internet, or local pharmacy), they will loose the benefit of one pharmacy or pharmacist knowing all the medications a patient is taking and ensuring that the medications will not result in harm to the patient. AB 74 and other bills that direct patients to multiple sources to obtain low cost drugs, may have the unintended result of putting peoples health at risk.

3) Drug Pricing. This bill requires DHS to provide price comparisons of commonly prescribed brand name prescription drugs, including typical prices charged by instate pharmacies, pharmacies in other states, and pharmacies in Canada. The problem with this requirement is it is impossible to come up with a "typical price charged" for a given drug. The true cost of a drug is influenced by factors including, but not limited to: discounts, rebates, and reimbursement formulas available to a particular purchaser, the number of manufacturers producing a given drug, and the supply and demand for a given drug in a given geographical area. In an effort to establish a benchmark for prescription drugs, standardized terms have been developed, however each term is limited in its ability to accurately establish the true price of prescription drugs. These terms include: average manufacturer price, average sales price, average wholesale price, federal supply schedule, and wholesale acquisition cost.

4) Substantive Amendments since the April 27th Board Meeting. Deletion of the provision that would require the hotline to provide information on prescription drug benefits available to Medicare beneficiaries, including the Voluntary Prescription Drug Benefit Program and the Medicare Prescription Drug Discount and Transitional Assistance Program.

6) History.

2005	
June 30	Assembly Rule 47.1 invoked. (Frommer)
June 29	In committee: Set, first hearing. Hearing canceled at the request of author.
June 23	From committee chair, with author's amendments: Amend, and re-refer to committee. Read second time, amended, and re-referred to Com. on HEALTH.
June 15	Referred to Com. on HEALTH.
June 6	In Senate. Read first time. To Com. on RLS. for assignment.
June 2	Read third time, passed, and to Senate. (Ayes 47. Noes 31. Page 2104.)
May 27	Read second time. To third reading.
May 26	From committee: Do pass. (Ayes 12. Noes 5.) (May 25).
May 4	In committee: Set, first hearing. Referred to APPR. suspense file.

Apr. 27	From committee: Do pass, and re-refer to Com. on APPR.Re-referred. (Ayes 7. Noes 1.) (April 26).
Apr. 21	Re-referred to Com. on B. & P.
Apr. 20	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
Apr. 13	From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes 10. Noes 4.) (April 12).
Apr. 7	Re-referred to Com. on HEALTH.
Apr. 6	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Coms. on HEALTH and B. & P.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

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AMENDED IN ASSEMBLY MAY 26, 2005

AMENDED IN ASSEMBLY MAY 2, 2005

AMENDED IN ASSEMBLY APRIL 19, 2005

AMENDED IN ASSEMBLY APRIL 5, 2005

CALIFORNIA LEGISLATURE—2005–06 REGULAR SESSION

ASSEMBLY BILL No. 75

Introduced by Assembly Members Frommer and Chan
(Principal coauthor: Assembly Member Baca)
(Coauthors: Assembly Members Bass, Berg, Cohn, Coto, De La Torre, Evans, Goldberg, Gordon, Hancock, Klehs, Koretz, Leno, Levine, Lieber, Nava, Pavley, Ridley-Thomas, Ruskin, Saldana, ~~and Salinas~~ *Salinas, and Torrico*)
(Coauthor: Senator Alquist)

January 3, 2005

An act to add Division 112 (commencing with Section 130500) to the Health and Safety Code, relating to prescription drugs.

LEGISLATIVE COUNSEL'S DIGEST

AB 75, as amended, Frommer. Pharmaceutical assistance program.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug manufacturers are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California Rx Plus State Pharmacy Assistance Program, to be administered by the department. The bill would authorize the department to negotiate drug rebate agreements

with drug manufacturers to provide for program drug discounts. The bill would authorize any licensed pharmacy or drug manufacturer to provide services under the program. The bill would establish eligibility criteria and application procedures for California residents to participate in the program. The bill would make it a misdemeanor for a person to intentionally make false declarations as to his or her eligibility or eligibility on behalf of any other person seeking eligibility. Because this bill would create a new crime, it would impose a state-mandated local program.

The bill would establish the California Rx Plus Program Fund, into which all payments received under the program would be deposited, with this fund to be used for the purpose of implementing the program, upon appropriation by the Legislature.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Division 112 (commencing with Section 130500) is added to the Health and Safety Code, to read:

DIVISION 112. CALIFORNIA RX PLUS STATE PHARMACY ASSISTANCE PROGRAM

CHAPTER 1. GENERAL PROVISIONS

130500. (a) This division shall be known, and may be cited, as the California Rx Plus State Pharmacy Assistance Program.

(b) For purposes of this division, the following definitions apply:

(1) "Department" means the State Department of Health Services.

(2) "Fund" means the California Rx Plus Program Fund.

(3) "Manufacturer" means a drug manufacturer, as defined in Section 4033 of the Business and Professions Code.

(4) "Program" means the California Rx Plus State Pharmacy Assistance Program.

(5) (A) "Qualified resident" means a resident of California who has a *gross* family income equal to or less than 400 percent of the federal poverty guidelines, as updated periodically in the Federal Register by the United States Department of Health and Human Services under the authority of Section 673(2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. Sec. 9902(2)).

(B) "Qualified resident" also means a resident of the state whose family incurs unreimbursed expenses for prescription drugs that equal 5 percent or more of *gross* family income or whose total unreimbursed medical expenses equal 15 percent or more of *gross* family income.

(C) For purposes of this paragraph, the cost of drugs provided under this division is considered an expense incurred by the family for eligibility determination purposes.

(6) "Resident" means a resident of California pursuant to Section 17014 of the Revenue and Taxation Code.

130501. There is hereby established in the State Department of Health Services, the California Rx Plus State Pharmacy Assistance Program.

CHAPTER 2. ELIGIBILITY AND APPLICATION PROCEDURES

130505. (a) To be eligible for the program, a person shall be a qualified resident, as defined in paragraph (4) of subdivision (b) of Section 130500 and shall not have outpatient prescription drug coverage paid for in whole or in part by the Medi-Cal program or the Healthy Families Program, or any other program that uses federal funds to pay part or all of the cost of the person's outpatient prescription drugs.

(b) Notwithstanding subdivision (a), a person enrolled in Medicare may participate in the program to the extent allowed by federal law for prescription drugs not covered by Medicare.

130506. (a) The department shall establish application forms and procedures for enrollment in the program. The application form shall include a requirement that the applicant or the

applicant's guardian or custodian attest that the information provided in the application is accurate to the best knowledge and belief of the applicant or the applicant's guardian or custodian.

(b) In assessing the income requirement for program eligibility, the department shall use the income information reported on the application and shall not require additional documentation.

(c) Any person who intentionally makes a false declaration as to his or her eligibility or any person who intentionally makes a false declaration as to eligibility on behalf of any other person seeking eligibility under this division for which that person is not eligible shall be guilty of a misdemeanor.

(d) Any person who intentionally makes a false declaration as to his or her eligibility or any person who intentionally makes a false declaration as to eligibility on behalf of any other person seeking eligibility under this division for which that person is not eligible may be denied a drug discount card under this program for up to one year from the date of the denial of coverage by the department.

(e) Upon determination of eligibility, the department shall mail the qualified resident a California Rx Plus Discount Card.

130507. (a) The department shall execute agreements with drug manufacturer patient assistance programs to provide a single point of entry for eligibility determination and claims processing for drugs available through those programs.

(b) The department shall develop a system to provide a participant under this division with the best discounts on prescription drugs that are available to the participant through this program or through a drug manufacturer patient assistance program.

(c) (1) The department may require an applicant to provide additional information to determine the applicant's eligibility for other discount card and patient assistance programs.

(2) The department shall not require an applicant to participate in a drug manufacturer patient assistance program or to disclose information that would determine the applicant's eligibility to participate in a drug manufacturer patient assistance program in order to participate in the program established pursuant to this division.

(d) In order to verify that California residents are being served by drug manufacturer patient assistance programs, the department shall require drug manufacturers to provide the department annually with all of the following information:

(1) The total value of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(2) The total number of prescriptions or 30-day supplies of the manufacturer's drugs provided at no or very low cost to California residents during the previous year.

(3) The total number of prescriptions or 30-day supplies, and total value, of each of the manufacturer's brand name drugs provided at no or very low cost to California residents during the previous year.

(e) The California Rx Plus Discount Card issued pursuant to subdivision (e) of Section 130506 shall serve as a single point of entry for drugs available pursuant to subdivision (a) and shall meet all legal requirements for a uniform prescription drug card pursuant to Section 1363.03.

CHAPTER 3. ADMINISTRATION AND SCOPE

130515. (a) The department shall conduct an outreach program to inform California residents of their opportunity to participate in the California Rx Plus State Pharmacy Assistance Program. The department shall implement an outreach, education, and enrollment program with Health Insurance Counseling and Advocacy Program agencies, the California Department of Aging and other state agencies, local agencies, and nonprofit organizations that serve residents who may qualify for the program.

(b) The department shall implement a plan to prevent the occurrence of fraud in the program.

130516. (a) Any pharmacy licensed pursuant to Chapter 9 (commencing with Section 4000) of Division 2 of the Business and Professions Code may participate in the program.

(b) Any drug manufacturer may participate in the program.

130517. (a) The amount a program participant pays for a drug through the program shall be equal to the participating provider's usual and customary charge or the pharmacy contract rate pursuant to subdivision (c), less a program discount for the

specific drug or an average discount for a group of drugs or all drugs covered by the program.

(b) In determining program discounts on individual drugs, the department shall take into account the rebates provided by the drug's manufacturer and the state's share of the discount.

(c) The department may contract with participating pharmacies for a rate other than the pharmacies' usual and customary rate.

130518. (a) The department shall negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program.

(b) The department shall seek to obtain an initial rebate amount equal to or greater than the rebate calculated under the Medi-Cal rebate program pursuant to Section 14105.33 of the Welfare and Institutions Code.

(c) Upon receipt of a determination from the federal Centers for Medicare and Medicaid Services that the program is a state pharmaceutical assistance program as provided in Section 130522, the department shall seek to contract for drug rebates that result in a net price lower than the Medicaid best price for drugs covered by the program.

(d) To obtain the most favorable discounts, the department may limit the number of drugs available through the program.

(e) All of the drug rebates negotiated pursuant to this section shall be used to reduce the cost of drugs purchased by participants in the program.

(f) Each drug rebate agreement shall do all of the following:

(1) Specify which of the manufacturer's drugs are included in the agreement.

(2) Permit the department to remove a drug from the agreement in the event of a dispute over the drug's utilization.

(3) Require the manufacturer to make a rebate payment to the department for each drug specified under paragraph (1) dispensed to a recipient.

(4) Require the rebate payment for a drug to be equal to the amount determined by multiplying the applicable per unit rebate by the number of units dispensed.

(5) Define a unit, for purposes of the agreement, in compliance with the standards set by the National Council of Prescription Drug Programs.

(6) Require the manufacturer to make the rebate payments to the department on at least a quarterly basis.

(7) Require the manufacturer to provide, upon the request of the department, documentation to validate that the per unit rebate provided complies with paragraph (4).

(8) Require the manufacturer to calculate and pay interest on late or unpaid rebates. The department may, by regulation, establish the date upon which the interest payments by drug manufacturers shall begin to accrue as well as any other regulations it deems necessary for the implementation of this paragraph.

(g) The department may collect prospective rebates from manufacturers for payment to pharmacies. The amount of the prospective rebate shall be contained in the drug rebate agreements executed pursuant to this section.

130519. (a) (1) The department may require prior authorization in the Medi-Cal program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8) for any drug of a manufacturer that does not agree to provide rebates to the department for prescription drugs purchased under this division, to the extent the department determines *that* it is appropriate to do *so* in order to encourage manufacturer participation in the program, ~~and~~ to the extent permitted by federal law, and subject to any necessary federal approvals or waivers.

(2) In making a determination to require prior authorization in the Medi-Cal program pursuant to paragraph (1), the department shall ensure that there are as many single-source drugs within each therapeutic category or subcategory as the department determines necessary to meet the health needs of the Medi-Cal population. In no event shall a Medi-Cal beneficiary be denied continued use of a drug that is part of a prescribed therapy unless that drug is no longer prescribed for that beneficiary.

(b) The names of manufacturers that do and do not enter into rebate agreements with the department pursuant to this division shall be public information and shall be released to the public.

130520. Contracts entered into for purposes of this division are exempt from Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code. Contracts with

pharmacies and drug manufacturers may be entered into on a bid or nonbid basis.

130522. The department shall seek a determination from the federal Centers for Medicare and Medicaid Services that the program established pursuant to this division complies with the requirements for a state pharmaceutical assistance program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r-8) and that discounts provided under the program are exempt from the Medicaid best price requirement.

130523. (a) The department shall deposit all payments the department receives pursuant to this division into the California Rx Plus Program Fund, which is hereby established in the State Treasury.

(b) Upon appropriation by the Legislature, moneys in the fund shall be used for the purpose of providing payment to participating pharmacies pursuant to Section 130517 and for defraying the costs of administering this division. Notwithstanding any other provision of law, no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.

(c) Notwithstanding Section 16305.7 of the Government Code, the fund shall also contain any interest accrued on moneys in the fund.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: AB 75 **VERSION: AMENDED MAY 26, 2005**

AUTHOR: FROMMER **SPONSOR: FROMMER**

RECOMMENDED POSITION:

SUBJECT: PHARMACEUTICAL ASSISTANCE PROGRAM

Existing Law:

Establishes within the Department of Health Services (DHS) a prescription drug discount program for Medicare recipients to enable recipients to obtain their prescription drugs at a cost no higher than the Medi-Cal reimbursement rates. (B&P 4425-4426)

This Bill:

1. Establishes the California Rx Plus State Pharmacy Assistance Program (Program) within DHS. (H&S 130501 Added)

2. Defines the terms: Program, Department (DHS), fund (California Rx Plus Program Fund), program, manufacturer (drug manufacturer), resident, and qualified resident. (H&S 130500 Added)

3. Establishes the criteria for a qualified resident as:

   a. A resident of California who has a family income equal to or less than 400 percent of the federal poverty guidelines. (2005 - $38,280 for an individual and $77,400 for a family of four)

   b. A family that incurs unreimbursed expenses for prescription drugs that equal 5 percent or more of family income or whose total unreimbursed medical expenses equal fifteen percent or more of family income. (H&S 130500 Added)

4. Allows an individual enrolled in Medicare to participate in the program to the extent allowed by federal law for prescription drugs not covered by Medicare. (H&S 130505 Added)

5. Requires DHS to conduct an outreach program to inform California residents of their opportunity to participate in program. Requires DHS to coordinate outreach activities with the California Department of Aging and other state agencies, local agencies, and nonprofit organizations that serve residents who may qualify for the program. (H&S 130515 Added)

6. Requires DHS to negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program and to seek rebates equal to or greater then Medi-Cal rebates. (H&S 130518 Added)

7. Requires that all of the drug rebates negotiated will be used to reduce the cost of drugs purchased by participants in the program. (H&S 130518 Added)

8. Establishes the California Rx Plus Program Fund, but does not appropriate funds to implement the program. (H&S 130523 Added)

9. Makes it a misdemeanor to falsify information to gain access to the program. Additionally, it bars a person for one year from the program if the person falsifies information to gain access to the program. (H&S 130506 Added)

Comment:

1) Author's Intent. The author is concerned about the high cost of prescription drugs and the inability of uninsured individuals to pay for their medications.

2) Cost of Prescription Drugs and the Uninsured. In 2002, American consumers paid $48.6 billion in out-of-pocket costs for prescription drugs, an increase of 15 percent over the previous year. National prescription drug spending has increased at double-digit rates in each of the past eight years, and increased 15 percent from 2001 to 2002.

The rising cost of prescription drugs has had a harmful effect on the health of people who are dependent on those drugs. A recent study by the RAND Corporation found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over twenty percent and experienced higher rates of emergency room visits and hospital stays.

Those who are uninsured for prescription drugs also suffer. A recent survey found that thirty-seven percent of the uninsured said that they did not fill a prescription because of cost, compared to 13 percent of the insured. A 2001 survey of seniors found that in the previous 12 months thirty- five percent of seniors without prescription drug coverage either did not fill a prescription or skipped doses in order to make the medicine last longer.

3) State Strategies for Reducing Cost of Drugs. Across the US two strategies have emerged at the state level to reduce the cost of prescription drugs for consumers.

The first strategy is to facilitate the importation of drugs from outside the US, primarily from Canada or the UK. Six states (Illinois, Minnesota, Rode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites. Additionally, 20 or more states, including California, have legislation pending to create either a Web site or phone line that would provide information on importing drugs from Canada.

The second strategy is to create drug discount programs. As of February 2005 at least 39 states have established or authorized some type of program to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Most programs utilize state funds to subsidize a portion of the costs, usually for a defined population that meets enrollment criteria, but an increasing number (22 states) have created or authorized programs that offer a discount only (no subsidy) programs for eligible or enrolled seniors; a majority of these states also have a separate subsidy program.

4) Related Legislation.

SB 19 (Ortiz) California Rx Program. This bill is sponsored by the Governor and would establish a state program to negotiate for lower price prescription drugs for lower income Californians. SB 19 failed to make it out of the Senate and is now a two-year bill.

5) Support / Opposition.

Support: AIDS Healthcare Foundation
Alzheimer's Association
American Federation of State, County and Municipal Employees
California Alliance for Retired Americans
California Federation of Labor
California Federation of Teachers
California Labor Federation
California Nurses Association
California Pharmacists Association
California Public Interest Research Group
Consumers Union
Health Access California
NAMI California (if amended)
Older Women's League of California
Retired Public Employees Association
Senior Action Network
Service Employees International Union

Opposition: BIOCOM
California Chamber of Commerce
Department of Health Services (unless amended)
National Association of Chain Drug Stores (unless amended)
Mental Health Association of California
Novartis Pharmaceuticals
Pharmaceutical Research and Manufacturers of America
Western Center on Law & Poverty
Wyeth Pharmaceuticals

6) History.

2005

June 28	In committee: Set, first hearing. Hearing canceled at the request of author.
June 15	Referred to Com. on HEALTH.
June 6	In Senate. Read first time. To Com. on RLS. for assignment.
June 2	Read third time, passed, and to Senate. (Ayes 43. Noes 34. Page 2141.)
May 27	Read second time. To third reading.
May 26	From committee: Amend, and do pass as amended. (Ayes 11. Noes 4.) (May 25). Read second time and amended. Ordered returned to second reading.
May 11	In committee: Set, first hearing. Referred to APPR. suspense file.
May 3	Re-referred to Com. on APPR.
May 2	Read second time and amended.
Apr. 28	From committee: Amend, and do pass as amended, and re-refer to Com. on APPR. (Ayes 7. Noes 1.) (April 26).
Apr. 20	Re-referred to Com. on B. & P.
Apr. 19	From committee chair, with author's amendments: Amend, and re-refer to Com. on B. & P. Read second time and amended.
Apr. 13	From committee: Do pass, and re-refer to Com. on B. & P. Re-referred. (Ayes 9. Noes 2.) (April 12).
Apr. 6	Re-referred to Com. on HEALTH.
Apr. 5	From committee chair, with author's amendments: Amend, and re-refer to Com. on HEALTH. Read second time and amended.
Jan. 18	Referred to Coms. on HEALTH and B. & P.
Jan. 4	From printer. May be heard in committee February 3.
Jan. 3	Read first time. To print.

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AMENDED IN SENATE APRIL 18, 2005

AMENDED IN SENATE JANUARY 6, 2005

SENATE BILL No. 19

Introduced by Senator Ortiz
(Principal coauthor: Senator Poochigian)

December 6, 2004

An act to add Division 112 (commencing with Section 130600) to the Health and Safety Code, relating to pharmacy~~—assistance,~~ *assistance,* and making an appropriation therefor.

LEGISLATIVE COUNSEL'S DIGEST

SB 19, as amended, Ortiz. California Rx Program.

Under existing law, the State Department of Health Services administers the Medi-Cal program, and is authorized, among other things, to enter into contracts with certain drug manufacturers. Under existing law, the department is entitled to drug rebates in accordance with certain conditions, and drug~~—manufactures~~ *manufacturers* are required to calculate and pay interest on late or unpaid rebates.

This bill would establish the California *State* Pharmacy Assistance Program (Cal Rx) under the oversight of the department. The bill would authorize the department to implement and administer Cal Rx through a contract with a 3rd-party vendor or utilizing existing health care service provider enrollment and payment mechanisms. The bill would require the department~~—or 3rd-party vendor~~ to attempt to negotiate~~-drug~~ *manufacturer* rebate agreements for Cal Rx with drug manufacturers. The bill would authorize any licensed pharmacy and any drug manufacturer, as defined, to provide services under Cal Rx. The bill would establish eligibility criteria and application procedures for California residents to participate in Cal Rx. The application process would require an applicant to attest to information provided

under penalty of perjury, which would expand the definition of an existing crime, thereby imposing a state-mandated local program. ~~The bill would authorize the department to terminate the program if any one of 3 determinations are made.~~

The bill would establish the California State Pharmacy Assistance Program Fund into which all payments received under Cal Rx would be deposited. The bill would continuously appropriate the fund to the department for purposes of Cal Rx.

The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: 2/3. Appropriation: yes. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

SECTION 1. Division 112 (commencing with Section 130600) is added to the Health and Safety Code, to read:

DIVISION 112. CALIFORNIA STATE PHARMACY ASSISTANCE PROGRAM (CAL RX)

CHAPTER 1. GENERAL PROVISIONS

130600. This division shall be known, and may be cited, as the California State Pharmacy Assistance Program or Cal Rx.

130601. For the purposes of this division, the following definitions shall apply:

(a) "Benchmark price" means the price for an individual drug or aggregate price for a group of drugs offered by a manufacturer equal to the lowest commercial price for the individual drug or group of drugs.

(b) "Cal Rx" means the California State Pharmacy Assistance Program.

(c) "Department" means the State Department of Health Services.

(d) "Fund" means the California State Pharmacy Assistance Program Fund.

(e) "Inpatient" means a person who has been admitted to a hospital for observation, diagnosis, or treatment and who is expected to remain overnight or longer.

(f) (1) "Lowest commercial price" means the lowest purchase price for an individual drug, including all discounts, rebates, or free goods, available to any wholesale or retail commercial class of trade in California.

(2) Lowest commercial price excludes purchases by government entities, purchases pursuant to Section 340B of the federal Public Health Services Act (42 U.S.C. Sec. 256b), or nominal prices as defined in federal Medicaid drug rebate agreements.

(3) A purchase price provided to an acute care hospital or acute care hospital pharmacy may be excluded if the prescription drug is used exclusively for an inpatient of the hospital.

(4) Wholesale or retail commercial class of trade includes distributors, retail pharmacies, pharmacy benefit managers, health maintenance organizations, or any entities that directly or indirectly sell prescription drugs to consumers through licensed retail pharmacies, physician offices, or clinics.

(g) "Manufacturer" means a drug manufacturer as defined in Section 4033 of the Business and Professions Code.

(h) ~~"Manufacturers~~ *"Manufacturer's* rebate" means the rebate for an individual drug or aggregate rebate for a group of drugs necessary to make the price for the drug ingredients equal to or less than the applicable benchmark price.

(i) *"Multiple-source drug" means the same drug in the same dosage form and strength manufactured by two or more manufacturers, which is approved by the United States Food and Drug Administration under provisions pertaining to the Abbreviated New Drug Applications (ANDA) process.*

(j) "National Drug Code" or "NDC" means the unique 10-digit, three-segment number assigned to each drug product listed under Section 510 of the federal Food, Drug, and Cosmetic Act (21 U.S.C. Sec. 360). This number identifies the labeler or vendor, product, and trade package.

(k) "Participating manufacturer" means a drug manufacturer that has contracted with the department to provide an individual

drug or group of drugs for Cal Rx participants at a price that is equal to or lower than the benchmark price.

(l) "Participating pharmacy" means a pharmacy that has executed a pharmacy provider agreement with the department for Cal Rx.

(m) "Pharmacy contract rate" means the negotiated per prescription reimbursement rate for drugs dispensed to Cal Rx recipients.

(n) "Prescription drug" means any drug that bears the legend: "Caution: federal law prohibits dispensing without prescription," "Rx only,"or words of similar import.

~~(j)~~

(o) "Private discount drug program" means a prescription drug discount card or manufacturer patient assistance program that provides discounted or free drugs to eligible individuals. For the purposes of this division, a private discount drug program is not considered insurance or a third-party payer program.

~~(k)~~

(p) "Recipient" means a resident that has completed an application and has been determined eligible for Cal Rx.

~~(l)~~

(q) "Resident" means a California resident pursuant to Section 17014 of the Revenue and Taxation Code.

~~(m) "Third-party vendor" means a public or private entity with whom the department contracts pursuant to subdivision (b) of Section 130602, which may include a pharmacy benefit administration or pharmacy benefit management company.~~

(r) "Therapeutic category" means a drug or a grouping of drugs determined by the department to have similar attributes and to be alternatives for the treatment of a specific disease or condition.

130602. (a) There is hereby established the California State Pharmacy Assistance Program or Cal Rx.

(b) The department shall provide oversight of Cal Rx. To implement and administer Cal Rx, the department may contract with a third-party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi-Cal program's fiscal intermediary.

(c) Any resident may enroll in Cal Rx if determined eligible pursuant to Section 130605.

CHAPTER 2. ELIGIBILITY AND APPLICATION PROCESS

130605. (a) To be eligible for Cal Rx, an individual shall meet all of the following requirements at the time of application and reapplication for the program:

(1) Be a resident.

(2) Have family income, as reported pursuant to Section 130606, that does not exceed 300 percent of the federal poverty guidelines, as revised annually by the United States Department of Health and Human Services in accordance with Section 673(2) of the Omnibus Budget Reconciliation Act of 1981 (42 U.S.C. Sec. 9902), as amended.

(3) Not have outpatient prescription drug coverage paid for in whole or in part by any of the following:

(A) A third-party payer. *An individual who has reached the annual limit on his or her outpatient prescription drug coverage provided by a third-party payer shall also be eligible for Cal Rx if he or she meets the eligibility requirements pursuant to paragraphs (1) and (2).*

(B) The Medi-Cal program.

(C) The children's health insurance program.

~~(D) The disability medical assistance program.~~

~~(E)~~

(D) Another health plan or pharmacy assistance program that uses state or federal funds to pay part or all of the cost of the individual's outpatient prescription drugs. Notwithstanding any other provision of this division to the contrary, an individual enrolled in Medicare may participate in this program, to the ~~extent allowed by federal law, for prescription drugs not covered by Medicare.~~ *extent allowed by federal law and consistent with federal state pharmacy assistance program standards, for prescription drugs not covered by Medicare prescription drug coverage or with respect to an individual responsible for paying 100 percent of the cost of prescription drugs under the coverage gap provisions of the Medicare Program prescription drug benefit.*

(4) Not have had outpatient prescription drug coverage specified in paragraph (3) during any of the three months preceding the month in which the application or reapplication for Cal Rx is made, unless any of the following applies:

(A) The third-party payer that paid all or part of the coverage filed for bankruptcy under the federal bankruptcy laws.

(B) The individual is no longer eligible for coverage provided through a retirement plan subject to protection under the Employee Retirement Income Security Act of 1974 (29 U.S.C. Sec. 1001), as amended.

(C) The individual is no longer eligible for the Medi-Cal program, children's health insurance program, or disability medical assistance program.

(D) The individual is no longer eligible for prescription drug coverage due to loss of employment and is not eligible for continued prescription drug coverage through the previous employer.

(b) Application and an annual reapplication for Cal Rx shall be made pursuant to subdivision (d) of Section 130606. An applicant, or a guardian or custodian of an applicant, may apply or reapply on behalf of the applicant and the applicant's spouse and children.

130606. (a) The department or third-party vendor shall develop an application and reapplication form for the determination of a resident's eligibility for Cal Rx.

(b) The application, at a minimum, shall do all of the following:

(1) Specify the information that an applicant or the applicant's representative must include in the application.

(2) Require that the applicant, or the applicant's guardian or custodian, attest that the information provided in the application is accurate to the best knowledge and belief of the applicant or the applicant's guardian or custodian.

(3) Include a statement printed in bold letters informing the applicant that knowingly making a false statement is punishable under penalty of perjury.

(4) Specify that the application and annual reapplication fee due upon submission of the ~~applicable form~~ *application form through a pharmacy, physician office, or clinic* is fifteen dollars ($15).

(c) In assessing the income requirement for Cal Rx eligibility, the department shall use the income information reported on the application and not require additional documentation.

(d) Application and annual reapplication may be made at any pharmacy, physician office, or clinic participating in Cal Rx~~,~~ ~~through a Web site or call center staffed by trained operators approved by the department, or through the third-party vendor.~~. A pharmacy, physician office, clinic, or third-party vendor completing the application shall keep the application fee as reimbursement for its processing costs. If it is determined that the applicant is already enrolled in Cal Rx, the fee shall be returned to the applicant and the applicant shall be informed of his or her current status as a recipient.

(e) *Application and annual reapplication may be made through a Web site or call center staffed by trained operators approved by the department.*

(f) The department or third-party vendor shall utilize a secure electronic application process that can be used by a pharmacy, physician office, or clinic, by a Web site, by a call center staffed by trained operators, or through the third-party vendor to enroll applicants in Cal Rx.

~~(f) During normal~~

(g) During the department's regular business hours, the department or third-party vendor shall make a determination of eligibility within four hours of receipt by Cal Rx of a completed application. The department or third-party vendor shall mail the recipient an identification card no later than four days after eligibility has been determined.

~~(g)~~

(h) For applications submitted through a pharmacy, the department or third-party vendor may issue a recipient identification number for eligible applicants to the pharmacy for immediate access to Cal Rx.

(i) Any person that signs and dates an application shall certify that the information in the application is true under penalty of perjury.

130607. (a) *The department shall encourage a participating manufacturer to maintain the level of private discount drug programs provided at a comparable level to that provided prior to the enactment of this division. To the extent possible, the department shall encourage a participating manufacturer to simplify the application and eligibility processes for its private discount drug program.*

(b) The department or third-party vendor shall attempt to execute agreements with private discount drug programs to provide a single point of entry for eligibility determination and claims processing for drugs available in those private discount drug programs.

~~(b)~~

(c) (1) Private discount drug programs may require an applicant to provide additional information, beyond that required by Cal Rx, to determine the applicant's eligibility for discount drug programs.

(2) An applicant shall not be, under any circumstances, required to participate in, or to disclose information that would determine the applicant's eligibility to participate in, private discount drug programs in order to participate in Cal Rx.

(3) Notwithstanding paragraph (2), an applicant may voluntarily disclose or provide information that may be necessary to determine eligibility for participation in a private drug discount program.

~~(c)~~

(d) For those drugs available pursuant to subdivision ~~(a)~~ *(b)*, the department or third-party vendor shall develop a system that provides a recipient with the best prescription drug discounts that are available to them through Cal Rx or through private discount drug programs.

~~(d)~~

(e) The recipient identification card issued pursuant to subdivision ~~(g)~~ *(h)* of Section 130606 shall serve as a single point of entry for drugs available pursuant to subdivision ~~(a)~~ *(b)* and shall meet all legal requirements for a uniform prescription drug card pursuant to Section 1363.03.

CHAPTER 3. ADMINISTRATION AND SCOPE

130615. (a) To the extent that funds are available, the department shall conduct outreach programs to inform residents about Cal Rx and private drug discount programs available through the single point of entry as specified in subdivisions ~~(a)~~ *(b)* and ~~(d)~~ *(e)* of Section 130607. No outreach material shall contain the name or likeness of a drug. The name of the organization sponsoring the material pursuant to subdivision (b)

may appear on the material once and in a font no larger than 10 point.

(b) The department may accept on behalf of the state any gift, bequest, or donation of outreach services or materials to inform residents about Cal Rx. Neither Section 11005 of the Government Code, nor any other law requiring approval by a state officer of a gift, bequest, or donation shall apply to these gifts, bequests, or donations. For purposes of this section, outreach services may include, but shall not be limited to, coordinating and implementing outreach efforts and plans. Outreach materials may include, but shall not be limited to, brochures, pamphlets, fliers, posters, advertisements, and other promotional items.

(c) An advertisement provided as a gift, bequest, or donation pursuant to this section shall be exempt from Article 5 (commencing with Section 11080) of Chapter 1 of Part 1 of Division 3 of Title 2 of the Government Code.

(d) The department may negotiate a contract with any manufacturer to provide funds as grants to nonprofit programs pursuant to Division 2 (commencing with Section 5000) of Title 1 of the Corporations Code, for the purpose of conducting outreach for Cal Rx.

130616. (a) Any pharmacy licensed pursuant to Article 7 (commencing with Section 4110) of Chapter 9 of Division 2 of the Business and Professions Code may participate in Cal Rx.

(b) Any manufacturer, as defined in subdivision (g) of Section 130601, may participate in Cal Rx.

130617. (a) This division shall apply only to prescription drugs dispensed to noninpatient recipients.

(b) The amount a recipient pays for a drug within Cal Rx shall be equal to the pharmacy contract rate pursuant to subdivision (c), plus a dispensing fee that shall be negotiated as part of the rate pursuant to subdivision (c), less the applicable ~~manufacturers~~ *manufacturer's* rebate.

(c) The department or third-party vendor may contract with participating pharmacies for a rate other than the pharmacist's usual and customary rate. However, the department must approve the contracted rate of a third-party vendor.

(d) The department or third-party vendor shall provide a claims processing system that complies with all of the following requirements:

(1) Charges a price that meets the requirements of subdivision (b).

(2) Provides the pharmacy with the dollar amount of the discount to be returned to the pharmacy.

(3) Provides a single point of entry for access to private discount drug programs pursuant to Section 130607.

(4) Provides drug utilization review warnings to pharmacies consistent with the drug utilization review standards outlined in Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8(g)).

(e) The department or third-party vendor shall pay a participating pharmacy the discount provided to recipients pursuant to subdivision (b) by a date that is not later than two weeks after the claim is received.

(f) The department or third-party vendor shall develop a program to prevent the occurrence of fraud in Cal Rx.

(g) The department or third-party vendor shall develop a mechanism for recipients to report problems or complaints regarding Cal Rx.

(h) A participating pharmacy is not precluded from offering the recipient a pharmacy contract reimbursement rate pursuant to subdivision (c) for prescription drugs produced by manufacturers not participating in Cal Rx.

130618. (a) In order to secure the discount required pursuant to subdivisions (b) and (c) of Section 130617, th~~e department or third-party vendor shall attempt to negotiate drug~~ *department shall attempt to negotiate manufacturer* rebate agreements for Cal Rx with drug manufacturers. *The department shall pursue manufacturer rebate agreements for all drugs in each therapeutic category.*

~~(b) Each drug rebate agreement shall do all of the following:~~

(b) Each participating manufacturer rebate agreement executed pursuant to this division shall do all of the following:

(1) Specify which of the *participating* manufacturer's drugs are included in the agreement.

(2) Permit the department to remove a drug from the agreement in the event of a dispute over the drug's utilization.

(3) Require the *participating* manufacturer to make a rebate payment to the department for each drug specified under paragraph (1) dispensed to a recipient.

(4) Require the rebate payment for a drug to be equal to the amount determined by multiplying the applicable per unit rebate by the number of units dispensed.

(5) Define a unit, for purposes of the agreement, in compliance with the standards set by the National Council of Prescription Drug Programs.

(6) Require the *participating* manufacturer to make the rebate payments to the department on at least a quarterly basis.

(7) Require the *participating* manufacturer to provide, upon the request of the department, documentation to validate that the per unit rebate provided complies with paragraph (4).

~~(8) Permit a~~

(8) Require the participating manufacturer to report to the department the lowest commercial price at the NDC level for each drug available through Cal Rx.

(9) Require the participating manufacturer to pay interest on late or unpaid rebates pursuant to subdivision (h).

(10) Permit a participating manufacturer to audit claims for the drugs the manufacturer provides under Cal Rx. Claims information provided to manufacturers shall comply with all federal and state privacy laws that protect a recipient's health information.

(11) Contain provisions for the timely reconciliation and payment of rebates and interest penalties on disputed units.

(12) Permit the department to audit or review participating manufacturer records and contracts as necessary to implement this division.

(c) To obtain the most favorable discounts, the department may limit the number of drugs available within Cal Rx.

(d) *To obtain the most favorable discounts on multiple-source drugs, the department may contract with private or public purchasing groups.*

(e) The entire amount of the drug rebates negotiated pursuant to this section shall go to reducing the cost to Cal Rx recipients of purchasing drugs. The Legislature shall annually appropriate an amount to cover the state's share of the discount provided by this section.

~~(e)~~

(f) The department or third-party vendor may collect prospective rebates from *participating* manufacturers for payment to pharmacies. The amount of the prospective rebate shall be contained in drug rebate agreements executed pursuant to this section.

~~(f) Drug rebate contracts negotiated by the third-party vendor shall be subject to review by the department. The department may cancel a contract that it finds not in the best interests of the state or Cal Rx recipients.~~

(g) The third-party vendor may directly collect rebates from manufacturers in order to facilitate the payment to pharmacies pursuant to subdivision (e) of Section 130617. The department shall develop a system to prevent diversion of funds collected by the third-party vendor.

(h) (1) A participating manufacturer shall calculate and pay interest on late or unpaid rebates.

(2) Interest described in paragraph (1) shall begin accruing 38 calendar days from the date of mailing the quarterly invoice, including supporting utilization data sent to the manufacturer. Interest shall continue to accrue until the date the manufacturer's payment is mailed.

(3) Interest rates and calculations for purposes of this subdivision shall be at ____ percent.

(i) A participating manufacturer shall clearly identify all rebates, interest, and other payments, and payment transmittal forms for Cal Rx, in a manner designated by the department.

130619. (a) The department or third-party vendor shall generate a monthly report that, at a minimum, provides all of the following:

(1) Drug utilization information.

(2) Amounts paid to pharmacies.

(3) Amounts of rebates collected from manufacturers.

(4) A Summary of the problems or complaints reported regarding Cal Rx.

(b) Information provided in paragraphs (1), (2), and (3) of subdivision (a) shall be at the national drug code level.

130620. (a) The department or third-party vendor shall deposit all payments received pursuant to Section 130618 into

the California State Pharmacy Assistance Program Fund, which is hereby established in the State Treasury.

(b) Notwithstanding Section 13340 of the Government Code, moneys in the fund are hereby appropriated to the department without regard to fiscal years for the purpose of providing payment to participating pharmacies pursuant to Section 130617 and for defraying the costs of administering Cal Rx. Notwithstanding any other provision of law, no money in the fund is available for expenditure for any other purpose or for loaning or transferring to any other fund, including the General Fund.

(c) Notwithstanding Section 16305.7 of the Government Code, any interest earned on any rebates collected from participating manufacturers on drugs purchased through Cal Rx implemented pursuant to this chapter shall be deposited in the fund exclusively to cover costs related to the purchase of drugs through Cal Rx.

130621. The department may hire any staff needed for the implementation and oversight of Cal Rx.

130622. The department shall seek and obtain confirmation from the federal Centers for Medicare and Medicaid Services that Cal Rx complies with the requirements for a state pharmaceutical assistance program pursuant to Section 1927 of the federal Social Security Act (42 U.S.C. Sec. 1396r–8) and that discounts provided under the program are exempt from Medicaid best price requirements.

130623. (a) Contracts and change orders entered into pursuant to this division and any project or systems development notice shall be exempt from all of the following:

(1) The competitive bidding requirements of State Administrative Manual Management Memo 03–10.

(2) Part 2 (commencing with Section 10100) of Division 2 of the Public Contract Code.

(3) Article 4 (commencing with Section 19130) of Chapter 5 of Part 2 of Division 5 of the Government Code.

(b) Change orders entered into pursuant to this division shall not require a contract amendment.

~~130624. The department may terminate Cal Rx if the department makes any one of the following determinations:~~

~~(a) That there are insufficient discounts to participants to make Cal Rx viable.~~

~~(b) That there are an insufficient number of applicants for Cal Rx.~~

~~(c) That the department is unable to find a responsible third-party vendor to administer Cal Rx.~~

(c) Drug rebate contracts entered into pursuant to this division are exempt from disclosure under the California Public Records Act (Chapter 3.5 (commencing with Section 6250) of Division 7 of Title 1 of the Government Code).

130625. Notwithstanding Chapter 3.5 (commencing with Section 11340) of Part 1 of Division 3 of Title 2 of the Government Code, the director may implement this division in whole or in part, by means of a provider bulletin or other similar instructions, without taking regulatory action.

SEC. 2. No reimbursement is required by this act pursuant to Section 6 of Article XIII B of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within the meaning of Section 6 of Article XIII B of the California Constitution.

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 19 **VERSION: AMENDED APRIL 18, 2005**

AUTHOR: ORTIZ **SPONSOR: DEPT. OF HEALTH SERVICE GOVERNOR**

RECOMMENDED POSITION:

SUBJECT: CALIFORNIA Rx PROGRAM

Existing Law:

Establishes within the Department of Health Services (DHS) a prescription drug discount program for Medicare recipients to enable recipients to obtain their prescription drugs at a cost no higher than the Medi-Cal reimbursement rates. (B&P 4425-4426)

This Bill:

1. Establishes the California State Pharmacy Assistance Program (Cal Rx, program) within the Department of Health Services (DHS). (H&S 130600 Added)

2. Permits DHS to contract with a third-party vendor or utilize existing health care service provider enrollment and payment mechanisms, including the Medi-Cal program's fiscal intermediary. (H&S 130602 Added)

3. Defines the terms: benchmark price, Cal Rx, fund, inpatient, lowest commercial price, manufacturer, manufacturer's rebate, prescription drug, private discount drug program, recipient, resident, third-party vendor, multiple-source drug, national drug code, participating manufacturer, participating pharmacy, pharmacy contract rate, and therapeutic category. (H&S 130600 Added)

4. Establishes eligibility criteria for the program as:

   a. A resident of California who has a family income does not exceed 300 percent of the federal poverty guidelines. (2005 - $28,710 for an individual and $58,050 for a family of four)

   b. A family that does not have outpatient prescription drug coverage paid for in whole or in part by any of the following: a third-party payer, the Medi-Cal program, the children's health insurance program, or another health plan or pharmacy assistance program that uses state or federal funds to pay part or all of the cost of the individual's outpatient prescription drugs. (H&S 130605Added)

5. Set a yearly fee of $15 for application or reapplication for the program. (H&S 130606 Added)

6. Requires DHS or third party vendor to establish a Web site and call center to use for applying for the program. Additionally requires DHS or third party vendor to determine eligibility for the program within four hours of receipt of a completed application. (H&S 130606 Added)

7. Permits DHS to conduct an outreach program to inform California residents of their opportunity to participate in program, if funds are available. (H&S 130615 Added)

8. Requires DHS to negotiate drug rebate agreements with drug manufacturer's to provide for discounts for prescription drugs purchased through the program. (H&S 130618 Added)

9. Sets the amount a recipient pays for a drug within program as equal to the pharmacy contract rate, plus a dispensing fee that shall be negotiated by DGS, less the applicable manufacturer's rebate. (H&S 130616 Added)

Comment:

1) Author's Intent. This bill is sponsored by the Governor and is in response to last year's veto of SB 1149 (Ortiz 2004). In his veto message the Governor stated, "A top priority of my Administration is to provide access to affordable prescription drugs. However, importing drugs from Canada or assisting residents in their efforts to do so would violate federal law and could expose the State to civil, criminal and tort liability. In an effort to bring significant price reductions to California's most at-risk consumers, my Administration put forward California Rx that seeks to provide real assistance to these Californians. California Rx represents an approach that harnesses the purchasing power of low-income seniors and uninsured Californians up to 300% of the federal poverty level ($28,710 for an individual and $58,050 for a family of four) to secure meaningful discounts in prescription drug costs. My Administration has begun negotiations with pharmaceutical companies regarding their participation in California Rx."

A fact sheet issued by the author's office states "In addition to the discounted drugs available to Cal Rx participants, Governor Schwarzenegger has secured a commitment from the Pharmaceutical Researchers and Manufacturers Association (PhRMA) to provide $10 million over the next two fiscal years to fund a clearinghouse to publicize and help Californians enroll in manufacturers' free and discount programs. The clearinghouse will provide Internet access and a toll-free multi-lingual call center to help thousands of Californians receive prescription drugs absolutely free, thereby saving them hundreds of millions of dollars per year. This element of the program does not require legislation and will begin operating in Spring 2005."

2) Cost of Prescription Drugs and the Uninsured. In 2002, American consumers paid $48.6 billion in out-of-pocket costs for prescription drugs, an increase of 15 percent over the previous year. National prescription drug spending has increased at double-digit rates in each of the past eight years, and increased 15 percent from 2001 to 2002.

The rising cost of prescription drugs has had a harmful effect on the health of people who are dependent on those drugs. A recent study by the RAND Corporation found that when out-of-pocket payments for prescription drugs doubled, patients with diabetes and asthma cut back on their use of drugs by over twenty percent and experienced higher rates of emergency room visits and hospital stays.

Those who are uninsured for prescription drugs also suffer. A recent survey found that thirty-seven percent of the uninsured said that they did not fill a prescription because of cost, compared to 13 percent of the insured. A 2001 survey of seniors found that in the previous 12 months thirty- five percent of seniors without prescription drug coverage either did not fill a prescription or skipped doses in order to make the medicine last longer.

3) State Strategies for Reducing Cost of Drugs. Across the US two strategies have emerged at the state level to reduce the cost of prescription drugs for consumers.

The first strategy is to facilitate the importation of drugs from outside the US, primarily from Canada or the UK. Six states (Illinois, Minnesota, Rode Island, Washington, and Wisconsin) have established Web sites with information and links about importing drugs from Canada and other countries. Some of these states require their Board of Pharmacy to license and inspect Canadian pharmacies prior to posting a link on their web sites. Additionally, 20 or more states, including California, have legislation pending to create either a Web site or phone line that would provide information on importing drugs from Canada.

The second strategy is to create drug discount programs. As of February 2005 at least 39 states have established or authorized some type of program to provide pharmaceutical coverage or assistance, primarily to low-income elderly or persons with disabilities who do not qualify for Medicaid. Most programs utilize state funds to subsidize a portion of the costs, usually for a defined population that meets enrollment criteria, but an increasing number (22 states) have created or authorized programs that offer a discount only (no subsidy) programs for eligible or enrolled seniors; a majority of these states also have a separate subsidy program.

4) Related Legislation.

AB 75 (Frommer) Pharmaceutical Assistance Program, would establish the California Rx Plus State Pharmacy Assistance Program within DHS. Requires DHS to negotiate drug rebate agreements with drug manufacturers to provide for discounts for prescription drugs purchased through the program. The measure establishes eligibility for the program for families with incomes equal to or less than 400 percent of the federal poverty guidelines.

5) Support / Opposition.

Support: State Department of Health Services (sponsor)
AARP
AIDS Healthcare Foundation
Alzheimer's Association
American Russian Medical Association
Asthma & Allergy Foundation of America
BayBio
BIOCOM
CA Academy of Family Physicians
CA Arthritis Foundation Council
CA Black Chamber of Commerce
CA Council of Community Mental Health Agencies
CA Healthcare Institute
CA Hepatitis C Task Force
CA Latino Medical Association
CA Medical Association
CA Pharmacists Association
CA Psychiatric Association
CA Society of Health-System Pharmacists
Down Syndrome Information Alliance
Epilepsy Foundation
Generic Pharmaceutical Association (if amended)
Gray Panthers California (if amended)
Hemophilia Council of California
Hispanic-American Allergy Asthma and Immunology Association
Lambda Letters Project
Mental Health Association in California
NAMI California
National Multiple Sclerosis Society - California Action Network
Novartis

Osteopathic Physicians and Surgeons of California
Pharmaceutical Research and Manufacturers of America
TMJ Society of California

Opposition: California Alliance for Retired Americans
California Federation of Teachers
California School Employees Association, AFL-CIO
International Alliance of Theatrical State
Employees, Moving Picture Technicians, Artists, and Allied Crafts of the United States
Amalgamated Transit Union Local 1555
Unless American Federation of Government Employees, Local 1061
American Federation of State, County, & Municipal Employees
American Federation of Television and Radio Arts
Butchers' Union Local 120
CA Conference Board of the Amalgamated Transit Union
CA Conference of Machinists
CA Labor Federation,
CA Nurses Association
CA Professional Firefighters
CA Public Interest Research Group
CA Teamsters Public Affairs Council
Central Labor Council of Butte, Contra Costa, and Glenn Counties
Consumer Federation of California
Communications Workers of America (CWA), Local 9412
CWA, Locals 9415, 9423, 9431, 9503, and 9586
Engineers and Scientists of California Local 20, IFPTE
Graphic Communications Union, Local 583
Greenlining Institute
Health Access California
Industrial, Technical and Professional Employees Union, Local 4873
International Alliance of Theatrical Stage Employees, Local 16
International Association of Machinists and Aerospace Workers, District Lodge 947
International Brotherhood of Electrical Workers (IBEW), Local 6 IBEW, Locals 45, 302, 441 and 569
International Cinematographers Guild Local 600
Ironworkers Locals 433 and 509
Kern County Fire Fighters Union Inc.
Laborers' International Union of North America
Laborers' International Union of North America, Local 89
League of United Latin American Citizens
National Association of Broadcast Employees and Technicians, Local 53
National Association of Chain Drug Stores
National Association of Letter Carriers, Golden Gate Branch 214, AFL-CIO
Northern California District Council - ILWU
Office of Professional Employees International Union, AFL-CIO, CLC
Orange County Central Labor Council, AFL-CIO
Plumbers and Pipefitters UA, Local 62
Professional and Technical Engineers, Local 21, IFPTE
Professional Musicians, Local 47
Sailors' Union of the Pacific
San Diego Imperial Counties Labor Council, AFL-CIO
San Francisco Labor Council, AFL-CIO
San Mateo Building and Construction Trades Council

San Mateo County Central Labor Council Santa Clara & San Benito Counties
Building & Construction Trades Council
Senior Action Network
Service Employees International Union (SEIU), AFL-CIO
SEIU, Locals 660, 1280, and 2028
SEIU of United Healthcare Workers - West
Sheet Metal Workers' International Association Local Unions 104 and 206
Southern California District Council of Laborers
Strategic Committee of Public Employees, Laborers International Union
Teamsters Local Unions 683 and 896
Teamsters Locals 912and 853
Teamsters Union Locals 572, 601, and 630
Transport Workers Union of America, AFL- CIO
Tri-Counties Central Labor Council
UFCW Locals 428, 1428, 1442, and 1179 UNITE-HERE! AFL-CIO UNITE-HERE! Locals 19 and 49
United Professional Firefighters of Contra Costa County,IAFF Local 1230
United Teachers Los Angeles

6) History.

2005	
May 4	Hearing postponed by committee.
Apr. 28	Set for hearing May 4 pending suspension of rules.
Apr. 27	Set, first hearing. Failed passage in committee. (Ayes 5. Noes 5. Page 845.) Reconsideration granted.
Apr. 21	Set for hearing April 27.
Apr. 20	Hearing postponed by committee.
Apr. 18	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
Apr. 14	Set for hearing April 20.
Apr. 13	Testimony taken. Hearing postponed by committee.
Mar. 17	Set for hearing April 13.
Jan. 27	To Com. on HEALTH.
Jan. 6	To Com. on RLS. From committee with author's amendments. Read second time. Amended. Re-referred to committee.
2004	
Dec. 7	From print. May be acted upon on or after January 6.
Dec. 6	Introduced. Read first time. To Com. on RLS. for assignment. To print.

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AMENDED IN ASSEMBLY JUNE 21, 2005

AMENDED IN SENATE APRIL 28, 2005

AMENDED IN SENATE APRIL 11, 2005

SENATE BILL No. 380

Introduced by Senator Alquist

February 17, 2005

An act to add Article 7 (commencing with Section 111657) to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, relating to drugs.

LEGISLATIVE COUNSEL'S DIGEST

SB 380, as amended, Alquist. Drugs: adverse event reporting.

The Sherman Food, Drug and Cosmetics Law provides for the regulation of various subjects relating to the processing, labeling, advertising, and sale of food, drugs, and cosmetics under the administration of the State Department of Health Services. A violation of these provisions is a crime.

This bill would require a licensed health professional and a health facility to report all suspected serious adverse drug events that are spontaneously discovered or observed in medical practice to MedWatch, the drug safety information and adverse event reporting program operated by the federal Food and Drug Administration (FDA), using the FDA 3500 Voluntary form developed by the FDA for MedWatch. The bill would prohibit a licensed health professional or health facility that violates this provision from being subject to the existing penalties and remedies of the Sherman Food, Drug and Cosmetics Law or any other provision of law.

Vote: majority. Appropriation: no. Fiscal committee: no. State-mandated local program: no.

The people of the State of California do enact as follows:

SECTION 1. The Legislature finds and declares all of the following:

(a) The federal Food and Drug Administration (FDA) operates a voluntary reporting system for adverse drug reactions known as the MedWatch system.

(b) The FDA currently estimates that only 10 percent of the adverse drug reactions or events that occur each year are reported to the FDA.

(c) Given the prevalence of pharmaceuticals and their use for treatment of hundreds of chronic diseases and conditions, and given recent highly publicized instances of commonly used prescription drugs being taken off the market due to safety concerns that were discovered after the drugs were approved for use, the systematic underreporting of adverse drug events represents a serious public health problem.

(d) Requiring licensed health professionals of organizations to report adverse drug events to the FDA would increase the amount of data available to the FDA about adverse drug reactions, thereby enabling the FDA to discern problems with drugs that arise after they are approved and to take action to protect the public health in a more timely manner.

SEC. 2. Article 7 (commencing with Section 111657) is added to Chapter 6 of Part 5 of Division 104 of the Health and Safety Code, to read:

Article 7. Adverse Event Reporting

111657. (a) A licensed health professional, including, but not limited to, a physician and surgeon, dentist, or pharmacist, and a health facility, including, but not limited to, a hospital or clinic, shall report all suspected serious adverse drug events that are spontaneously discovered or observed in medical practice to MedWatch, the drug safety information and adverse event reporting program operated by the federal Food and Drug Administration.

(b) For purposes of this section, serious adverse drug events shall include adverse health outcomes involving patients that result in death, life-threatening conditions, hospitalization,

disability, congenital anomaly, or required intervention to prevent permanent impairment or damage.

(c) Any health professional or health facility that is required to report an adverse drug event pursuant to this section shall do so using the FDA 3500 Voluntary form developed by the federal Food and Drug Administration for MedWatch.

111658. A licensed health professional or health facility that violates any provision of this article shall not be subject to the penalties and remedies outlined in Chapter 8 (commencing with Section 111825) or any other provision of law. *Nothing in this section affects otherwise existing duties, rights, or remedies under the law.*

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CALIFORNIA STATE BOARD OF PHARMACY
BILL ANALYSIS

BILL NUMBER: SB 380 **VERSION: AMENDED APRIL 28, 2005**

AUTHOR: ALQUIST **SPONSOR: SENIOR CITIZENS, SO. CAL**

RECOMMENDED POSITION: NO POSITION

SUBJECT: DRUGS: ADVERSE EVENT REPORTING

Existing Law:

The Federal Food, Drug, and Cosmetic Act and the Modernization Act establish the Food and Drug Administration's (FDA) postmarketing and risk assessment programs for adverse drug reactions. The laws also establish mandatory reporting requirements for drug manufactures to report adverse drug reactions.

This Bill:

1) Requires a licensed health professional, (a physician and surgeon, dentist, or pharmacist), and a health facility, (a hospital or clinic), to report all suspected serious adverse drug events that are spontaneous or observed in medical practice to the FDA's MedWatch program.

2) Requires the report to be made using FDA 3500, Voluntary form.

3) Defines a serious adverse drug events as, adverse health outcomes involving patients that result in death, life-threatening conditions, hospitalization, disability, congenital anomaly, or required intervention to prevent permanent impairment or damage.

4) Provides that a person or health facility that violates any provision of the measure would not be subject to penalties and remedies in H&S 111825 or any other provisions in law. (Penalties under H&S 111825 are imprisonment for not more than one year in the county jail or a fine of not more than $1,000, or both the imprisonment and fine.)

(H&S 111657 Added)

Comment:

1) Author's Intent. The author is concerned that the FDA may not be receiving enough information about adverse drug reactions to make informed decisions to protect the public health.

2) Enforcement. This bill lacks language that would make the bill enforceable. There is no way to know how many adverse drug reactions a health professional observes each year. Consequently this bill would be impossible to enforce. Additionally, it is unclear how each regulatory board would know that an event should have been reported, but wasn't.

3) FDA's MedWatch Program. MedWatch is a voluntary reporting program run by the FDA that allows healthcare professionals and consumers to report serious problems that they suspect are associated with the drugs and medical devices they prescribe, dispense, or use.

Reporting is done on line, by phone, or by submitting the MedWatch 3500 form by mail or fax. The FDA disseminates medical product safety alerts, recalls, withdrawals, and important labeling changes to the medical community and the general public via its web site and the Med Watch E-list.

4) Drugmakers Plans for Voluntary Disclosure on the Internet. Reuters News reported on May 16, 2005 that the pharmaceutical industry plans to launch a global website in September 2005, pooling information on ongoing and completed clinical trials. Additionally, in January 2005, drugmakers in the United States, Europe, and Japan agreed on a voluntary code to publish detailed clinical trials data. Data would be available through a single website with links to company websites and other commercial and government-sponsored websites containing information provided by firms. The voluntary code is backed by Pfizer Inc, GlaxoSmithKline Plc, Merck, AstraZeneca Plc, Novartis AG and Sanofi-Aventis SA.

5) Other Legislation. Two other bills dealing with drug safety and reporting requirements have been introduced this session.

AB 71 (Chan) Office of California Drug Safety Watch, would require DHS to 1) establish a central repository of information about the safety and effectiveness of prescription drugs; and 2) disseminate information to health care professionals and consumers through a Web site that would include links to other relevant web-based information that has been professionally reviewed and approved.

SB 329 (Cedillo) California Prescription Drug Safety and Effectiveness Commission. This is a spot bill and will be amended for other purposes.

6) Federal Legislation. On May 4, 2005, Congressman Hinchey introduced H.R. 2090, the Food and Drug Administration Improvement Act of 2005. This bill would: 1) establish within the FDA a Center for Postmarket Drug Safety and Effectiveness to monitor all approved drugs as well as all advertisements and promotions associated with those products; 2) prohibit the FDA from collecting fees paid by companies it regulates and instead, deposit those funds into the general fund of the Treasury; 3) empower the FDA with the authority to mandate that companies conduct post-marketing studies of FDA-approved drugs; and 4) enable the FDA to mandate changes to labels of FDA-approved products if a new risk is discovered. HR 2090 has been referred to the House Committee on Energy and Commerce.

7) Support & Opposition.

Support: American Federation of State, County and Municipal Employees
California Alliance for Retired Americans
California Labor Federation
California Psychological Association
California Public Interest Research Group
Congress of California Seniors
Consumers Union
Greenlining Institute
Health Access California
Protection and Advocacy, Inc.

Opposition: American College of Obstetricians and Gynecologists, Region IX
California Hospital Association
California Medical Association
California Society of Health-System Pharmacists
Kaiser Permanente

8) History.

2005

June 29	From committee: Do pass, but first be re-referred to Com. on APPR. (Ayes 7. Noes 0.) Re-referred to Com. on APPR.
June 21	From committee with author's amendments. Read second time. Amended. Re-referred to committee.
June 15	From committee: Do pass, but first be re-referred to Com. on B. & P. (Ayes 9. Noes 4.) Re-referred to Com. on B. & P.
June 7	Set, first hearing. Hearing canceled at the request of author.
May 26	To Coms. on HEALTH and B. & P.
May 2	In Assembly. Read first time. Held at Desk.
May 2	Read third time. Passed. (Ayes 23. Noes 13. Page 867.) To Assembly.
Apr. 28	Read second time. Amended. To third reading.
Apr. 27	From committee: Do pass as amended. (Ayes 9. Noes 2. Page 767.)
Apr. 18	Set for hearing April 25.
Apr. 11	Read second time. Amended. Re-referred to Com. on APPR.
Apr. 7	From committee: Do pass as amended, but first amend, and re-refer to Com. on APPR. (Ayes 7. Noes 3. Page 411.)
Mar. 14	Set for hearing March 30.
Feb. 24	To Com. on HEALTH.
Feb. 18	From print. May be acted upon on or after March 20.
Feb. 17	Introduced. Read first time. To Com. on RLS. for assignment. To print.

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